

EXHIBIT B

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO: <i>Wave 8 Cases</i>	

GENERAL EXPERT REPORT OF DOROTHY KAMMERER-DOAK, M.D.

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Report regarding the TVT mid-urethral sling

This report contains my opinions regarding the safety and efficacy of the Ethicon design of the TVT device, the content of the device's labeling, and the bases for my opinions. My opinions are based on my education, training, and experience in the field of urogynecology, on the materials discussed and/or cited in this report, and on the materials included on the attached list of materials reviewed. I hold the opinions in this report to a reasonable degree of medical certainty, and reserve the right to supplement or amend my opinions, if necessary, upon the receipt of additional information. I am being compensated \$350 per hour for record review and report preparation, \$550 per hour for deposition time, and \$750 per hour for trial testimony.

I. Background

I graduated from the University of California, Davis Medical School in 1988 and underwent a residency at the University of California, Irvine in Obstetrics and Gynecology from 1988-1992. During my residency, I was trained in the evaluation and management of pelvic floor disorders including stress urinary incontinence (SUI), including both surgical and non-surgical treatments. The three most common procedures for uncomplicated SUI at that time were the anterior colporrhaphy with Kelly plication (K-P), the modified Pereyra needle urethropexy, and the Burch urethropexy, and I learned all three. A randomized controlled trial published in 1989 that compared these 3 procedures (Bergman A Am J Ob Gynecol 1989; 160:1102-6) demonstrated significantly greater cure with the Burch compared to the other 2 procedures. However, as the Burch urethropexy is performed through an abdominal incision, and the other 2 are either mostly or are completely performed vaginally, both the K-P and the modified Pereyra procedures were still commonly used. The Burch procedure, however, may not be adequate for recurrent or persistent SUI or with SUI in the presence of low pressure urethra/intrinsic sphincteric deficiency. A sub-urethral sling is recommended in these cases of severe urinary incontinence to give greater resolution of SUI (Bent Clin Obstet Gynecol 1990;33:358-66). In those days, the sling material was harvested from the patient's abdominal wall fascia or from the thigh fascia lata. Both of these harvesting techniques require additional time for the procedure, larger incisions and increased surgical morbidity. The use of synthetic mesh with Gore-Tex or Marlex was quickly abandoned due to high rates of complications related to the character of the mesh.

During my residency, I discovered an affinity for surgery and its life-altering nature by improving patients' quality of life. I decided to pursue a fellowship in urogynecology/pelvic floor disorders, and was fortunate to be accepted into a fellowship program at the Mayo Clinic Scottsdale in 1992. I was mentored by both a gynecologist, Dr. Javier Magrina, and a urogynecologist, Dr. Jeffrey Cornella. During my training, I operated almost 5 days a week, often until 10 PM or later, and was the sole

fellow in the program. I was further trained in all surgical treatments of SUI including the K-P, the Pereyra procedure, the Burch, and sub-urethral slings from patient-harvested thigh fascia lata or abdominal wall fascia. Additionally, I was trained in the Marshall-Marchetti-Krantz (MMK) procedure, which is similar to the Burch, but uses the cartilage and peri-osteum of the pubic bone to anchor the supporting sutures rather than Cooper's ligament as does the Burch. Several patients developed osteitis pubis/osteomyelitis, a debilitating inflammation or infection of the pubic bone as a direct result of the MMK, and so this procedure was abandoned as an option for me in my practice (Kammerer-Doak *Am J Obstet Gynecol* 1998;179:586).

Following graduation from my fellowship, I pursued a position in academic medicine at the University of New Mexico Hospital (UNMH) Department of Obstetrics and Gynecology. Urogynecology and pelvic floor medicine was a nascent sub-specialty, and as such, did not exist at UNMH. During my time there, I developed a program to train the residents in urogynecology, including the performance of Burch procedure as only the K-P anterior repair was being used to surgically treat SUI at UNMH at that time despite the evidence from the literature. I instigated a randomized, controlled trial that also compared these 2 procedures, which again, demonstrated the superiority of the Burch over the K-P. (Kammerer-Doak *Obstet Gynecol* 93 (1):75-78 (1999)). The pubovaginal suburethral sling continued to be used for recurrent or severe SUI, using harvested abdominal wall fascia or thigh fascia lata. In 1998, the first report of the use of cadaveric fascia lata for slings was published (Wright *J Urol* 160:759), which removed the morbidity of harvesting fascia from the patient. However, its use was quickly abandoned secondary to complications of both erosion as well as reabsorption resulting in higher failure (Kammerer-Doak *Int Urogynecol J Pel Floor Dis* 2002;13:106 and Soergel *Int Urogynecol J Pelvic Floor Dysfunct* 2001;12:247). So, while the Burch was the accepted procedure with the highest success for uncomplicated SUI, and the pubovaginal suburethral sling for recurrent or severe SUI, the ideal material to be used for the sling had yet to be found. A modification of the abdominal fascial sling using a suture bridge, rather than a complete fascial sling to traverse from the abdominal wall, beneath the urethra, and back up to the abdominal wall was then developed, a combination of the modified Pereyra procedure, and the complete sling: the "string sling", in which an approximate 6-7 cm by 2-3 cm piece of abdominal wall fascia was harvested through a smaller abdominal incision, transplanted and sutured into place under the urethral vaginally, and then attached to the abdominal wall fascia using permanent sutures brought through the space of Retzius using the Pereyra needles. This "string sling" still required an abdominal incision for harvesting, and significant dissection into the retropubic space to allow passage of the Pereyra needle, which was guided by one's finger and carried inherent risks of bladder injury, bleeding, and prolonged voiding dysfunction, and relied on permanent sutures to complete the sling.

The first studies about the TVT sling were published in the late 1990s (Ulmsten), but I did not adopt the use of the TVT sling until the Ward and Hilton RCT comparing the TVT sling to the Burch procedure with 2 years of follow up was published in 2004, demonstrating equivalent success, but with decreased operative morbidity with the TVT sling (*Am J Obstet Gynecol* 190:324). I counseled my patients about the risks and benefits of both procedures, and the overwhelming majority chose the TVT sling. When

I started using the TVT sling, I was mentored by both Dr. Rebecca Rogers from UNMH, and one of my partners who had learned the procedure in her residency. Because I had performed many traditional slings, the TVT sling procedure was not difficult for me to learn. Since that time, I have performed approximately 2000 TVT slings, both in isolation for the surgical treatment of SUI as well as in combination with pelvic organ prolapse (POP) repairs. I have taught residents and fellows how to perform the TVT sling, and have been an invited lecturer to train my colleagues through courses at the American College of Obstetrics and Gynecology as well as through UNMH and the New England Obstetrical and Gynecologic Society continuing medical educational courses.

Throughout my career, I have practiced evidence-based medicine to the best of my ability, and my research and publications reflect this, with several randomized, controlled trials in addition to the one listed above. I have also been critical of my work, carefully examining and evaluating complications, as also evidenced in the above publications. While on faculty at UNMH, I was fortunate to mentor many of the OBGYN residents, and one of them, Dr. Rebecca Rogers, decided to pursue a fellowship in Urogynecology, and asked me if we could develop a fellowship program in Urogynecology/Female Pelvic Medicine and Reconstructive Surgery (FPMRS) at UNMH. After obtaining the American Board of Obstetrics and Gynecology guidelines, a fellowship was commenced with Dr. Rogers as the first fellow, and since that time, has developed into one of the leading fellowships in FPMRS in the United States. Her senior research project under my mentorship was the development of what is now the most widely utilized sexual function questionnaire for women with pelvic organ prolapse and urinary incontinence, the Pelvic Organ Prolapse and Urinary Incontinence Sexual Function Questionnaire (PISQ) (Rogers, Kammerer-Doak Am J Obstet Gynecol 184:552-558 (2001). The PISQ assesses the effect of both SUI and POP on sexual function and found decreased sexual function in women with these disorders compared to those without (Rogers Int J Urogynecol 12:361-365(2001).

I left UNMH in 1999 after obtaining my tenure for a position with a health maintenance organization, Lovelace Medicine Systems, as I found that what I loved about the practice of medicine was direct patient contact and surgical care. However, I was still able to train and teach the FPMRS fellows as well as UNMH residents who rotated through our system for 2 months during their 3rd and 4th years. I went into private practice to focus on gynecology and FPMRS in 2009, and continued to train the fellows until 2011 when UNMH expanded their Urogynecology division. I remained active with UNMH as a collaborator in research projects, including a revision of the PISQ through the International Urogynecology Association (IUGA), the PISQ- IUGA revised (PISQ-IR), {Int Urogynecol J. 2013 Jul;24(7):1091-103}.

I am a member of the American Urogynecologic Society (AUGS) as well as the International Urogynecological Association (IUGA) and served as chair of the IUGA Research and Development Committee for five years. During my tenure as chair of the IUGA R&D committee we completed the PISQ-IR, as well as three IUGA R&D Committee Opinions, which are an evidence based review of the literature regarding various topics in FPMRS (Kammerer-Doak Int Urogynecol J 2014;10:1303-12, Bazi Int Urogynecol J 2016 Mar 12 [Epub ahead of print], and Ismail Int Urogynecol J 2016 Jul 5

[Epub ahead of print] and a survey of practice patterns for the surgical treatment of SUI and POP of the IUGA membership (Kammerer-Doak Int Urogynecol J. 2016 Oct 17[Epub ahead of print]). This survey of the international membership who focus on treating women with pelvic floor disorders including SUI found that, for 91% of the survey respondents, the preferred method for the surgical treatment of SUI was the mid-urethral sling.

When urogynecology became an American College of Obstetrics and Gynecology recognized subspecialty, Female Pelvic Medicine and Reconstructive Surgery (FPMRS) in 2014, I qualified to sit the examination, passed on my first attempt, and am now doubly boarded in both OBGYN and FPMRS.

My curriculum vitae is attached to this report. I have not provided expert testimony in the previous four years.

II. Urinary Incontinence in General

There are two main types of urinary incontinence: stress urinary incontinence (SUI), and overactive bladder (OAB). SUI is due to loss of support under the urethra, as well as a deficiency of the internal, intrinsic urethral sphincteric mechanism and results in urine loss with increases in abdominal pressure, such as with cough, sneeze, and exercise. OAB is associated with urinary urgency, frequency, and urge incontinence episodes due to loss of voluntary bladder control. Mixed urinary incontinence (MUI) is also common, in which women suffer with both OAB and SUI. The TVT sling is an option to treat SUI and MUI in which SUI is pre-dominant, but not OAB or MUI in which OAB is pre-dominant

The prevalence of urinary incontinence in community dwelling women varies from 10-50% depending on the population studied as well as the definition used, with 30% a reasonable estimate. (vanGeelan S Eur Clinics Obstet Gynecol 2005;1:3) About 8% of women suffer from UI that is severe and bothersome.

UI affects all aspects of patients' quality of life ("QOL"), including intimacy, with women avoiding intercourse or being embarrassed to participate in intercourse due to fears of urinary leakage. Coital incontinence is particularly bothersome to women, and is associated with even greater effect on QOL and well-being than those with UI and no coital incontinence. Sexual function is significantly lower in women with UI than those without. (Rogers, Kammerer-Doak In J Urogynecol 2001;12:361-365.) Additionally, women with UI avoid physical activity and social events as a result of their incontinence. Women with UI have lower well-being related to the impact of the UI on behavior, embarrassment associated with the UI, as well as the frequency of leakage episodes. (Smith, BMC Urol 2016 May 23;16(1):22.) While UI is not a life-threatening condition, UI is associated with significant impact on QOL similar to individuals suffering from chronic diseases such as those with pulmonary issues who require oxygen (Charalambous Pelviperineology 2009;28:51). Depression, feelings of isolation, shame, loss of self-confidence and self-esteem are all impacts of UI. UI is associated with other physical issues, including perineal skin irritation, infections, and even ulcerations. There

is also a significant cost for urinary incontinence associated with pad use, increased laundry needs, physician visits, and complications related to UI. The estimated annual direct cost of UI in the United States in 1995 dollars was \$12.4 billion. (Wilson L. *Obstet Gynecol* 2001;98:398.)

III. The Treatment of Stress Urinary Incontinence

a. Nonsurgical options and their effectiveness

Nonsurgical options for the treatment of SUI include pelvic floor muscle training, or Kegel exercises, and continence pessaries. Supervised, structured pelvic floor muscle training through physical therapy to strengthen the extrinsic urethral sphincter and pubo-coccygeus muscles results in cure of SUI or improvement in about 56%, but with only short term follow up. (Dumoulin *Cochrane Database Syst Rev* 2014;14(5) and *Neurourol Urodyn* 2015;34:300.) However, the long-term benefits of Kegels, greater than one year, have not been well-studied, with only two small studies assessing results at one year. At ten years, following participation in a study involving conservative treatment of SUI, only 15% had continued with Kegel exercises, and 47% had undergone surgery for SUI. Of the women who did not undergo surgery for SUI, 94% were still incontinent. (Schiotz *Int Urogyn J* 2008;19:911.) Continence pessaries for the treatment of SUI give lower success than behavioral treatment which included Kegel exercises as well as coping strategies, with only 35% reporting no bothersome SUI symptoms with pessary use at one year, compared to 40% with behavioral therapy. (Richter *Obstet Gynecol* 2010;115:609.) Importantly, successful treatment of SUI decreased from 3 to 12 months, emphasizing the importance of assessing long-term outcomes. Additionally, at one year, only 45% of women continued to use the pessary, and only 57% continued to perform their Kegel exercises.

b. Surgical options and their effectiveness

Based on the current theories of stress continence, the goal of the surgical treatment of SUI is to re-establish a layer of support under the urethra against which the urethra is compressed closed with increases in intra-abdominal pressure.

- i. **Anterior colporrhaphy and Kelly plication**—this procedure is performed vaginally. A large incision is made extending from near the urethral meatus along almost the entire length of the anterior vagina as the KP is typically combined with an anterior colporrhaphy. The vaginal mucosa is then dissected away from the underlying connective tissue to the pubic bone laterally, and at the level of the urethral vesical junction (UVJ), almost to the Space of Retzius. The tissues under the UVJ are then plicated using absorbable sutures, with the goal of restoring a retropubic position of the UVJ. While the K-P was utilized for years due to its vaginal approach and concurrent repair of cystocele, as listed above, the KP is associated with a very low 5-year cure for SUI.

- ii. **MMK**—The Marshall-Marchetti-Krantz procedure is performed through an abdominal incision. Sutures are placed into the periurethral tissues and then through the periosteum of the pubic bone to elevate the urethra into an intra-abdominal position. Its use is rare, because, as listed above, the MMK is associated with risk for osteitis pubis/osteomyelitis and offers no advantage over the Burch procedure.
- iii. **Autologous pubo-vaginal fascial slings**—fascia is harvested from either an abdominal incision for abdominal wall fascia, or from a thigh incision for fascia lata sling. A vaginal incision is made along almost the entire length of the anterior vagina beginning inferior to the urethral meatus, and the vaginal mucosa is dissected away from the underlying connective tissue to the border of the pubic bone at the level of the UVJ. The retropubic space is entered by penetrating the urogenital membrane. The fascial sling is passed from the vagina, through the retropubic space, and into the abdomen bilaterally. The sling is anchored to the abdominal fascia or the pubic bone, and vaginally, is attached to the connective tissue at the level of the UVJ to re-establish a layer of support under the urethra. Autologous pubo-vaginal fascial slings require additional incisions for harvesting, and are therefore associated with increased operative morbidity. The harvest of fascia lata is associated with a 1% incidence for hematoma, 3% for wound seroma requiring drainage, and 7% for wound cellulitis requiring antibiotics, as well as long term 13% patient dissatisfaction due to unacceptable cosmesis and/or leg discomfort, and 5% with clinically significant symptoms including pain. Abdominal fascial slings have a lower failure rate than the Burch in RCTs, but with increased risks only for OAB and voiding difficulties. (Albo N Engl J Med 2007 and Brubaker J Urol 2012.) In this trial, 18.5% had wound complications not requiring surgery, 52 (6.9%) ureteral injury, and 12 (1.6%) cystotomy. One patient in the Burch group had suture erosion into the bladder, and another, also from the Burch group, a ureterovaginal fistula. Pelvic pain was not significantly different between those who had the fascial sling compared to the Burch, < 1% in both groups.
- iv. **Burch procedure**—this surgical treatment of SUI was introduced in 1961 as an alternative to the MMK. The Burch procedure requires an abdominal approach to access the retropubic space, either through an incision, or laparoscopically. Sutures are placed into the peri-urethral tissues and then brought through Cooper's ligament on the back of the pubic bone, using this tissue and the tension applied by the sutures to re-create a hammock of support under the urethra. However, the original goal of the Burch was to restore the UVJ to an intra-abdominal position to improve pressure

transmission. Based on the current theories of stress continence, the Burch functions to re-establish support under the urethra, which is compressed closed against this layer with increases in intra-abdominal pressure. As outlined previously, the Burch cures SUI 69-88% and is superior to needle suspensions and anterior repair with Kelley plication, but inferior to abdominal wall fascial slings. In most studies, cure rates decrease with time. (Kjølhede P, *Acta Obstet Gynecol Scand* 2005;84:767-72; Demirci F, et al., *Gynecol Obstet Invest* 2001;51:243-247; Alcalay M and Stanton SL, *BJOG* 1995;102:740-45; Albo N *Engl J Med* 2007; Richter HE, et al., *J. Urol.* 2012;188:485-89.) A recent Cochrane review noted cure at 5 years to decline to about 70%. (Lapitan Cochrane Database Syst Rev 2016;15:2.)

- v. **Mid-urethral slings**—Due to the surgical morbidity of harvesting autologous material for slings, the search for alternative material to utilize for the sling led to the use of mesh, xenografts and allografts in the 1980s and 1990s. The use of Gore-Tex and Marlex mesh was quickly abandoned due to wound complications associated with these microporous materials (Weinberger *Obstet Gynecol.* 1995; 86:92). Allograft cadaveric fascia lata and xenoform grafts using materials such as porcine dermis were associated with high rates of failure probably secondary to reabsorption of these substances. (Carbone *J Urol* 2001;165:1604.)

Traditional slings, regardless of material used, were reserved for women with severe and/or recurrent urinary incontinence due to higher surgical morbidity as well as post-operative voiding complications as compared to the Burch. (Novara 2010 and Schimpf 2014). They were also traditionally placed at the UVJ based on the prevailing theory of stress continence of restoring an intra-abdominal position of the UVJ and improving pressure-transmission ratios. Two new theories of stress continence, The “Hammock Hypothesis” based on anatomical studies performed by Dr. John DeLancey, and the “Integral Theory” based on physiodynamic studies led by Drs. Peter Petros and Ulf Ulmsten suggested the mid-urethra was the area of importance rather than the retropubic position of the UVJ. These landmark scientific investigations led to the development of the midurethral sling in the 1990s. Based on our current understanding of the surgical treatment of SUI, the goal of the procedure is re-establish a layer of support under the mid-urethra, against which the urethra is compressed closed with increases in intra-abdominal pressure.

IV. Ethicon's TVT Device

a. Historical Background

Mesh has longed been used in human surgery, beginning with abdominal hernia and aneurysm repairs in the 1960s. Based on randomized controlled trials (RCTs), the use of mesh for hernia is considered standard of care resulting in statistically significant increased success compared to suture hernia repair. Mesh also has a long use in urogynecology dating back to the 1950s for the treatment of vaginal vault prolapse with the abdominosacrocolpopexy (ASC). Initially, material such as Gore-Tex and Marlex were used, but the now known morbidity of these meshes included higher rates of mesh exposure and infection. Therefore, just as the traditional slings were reserved for recurrent and severe SUI, the ASC was reserved for recurrent and severe cases of vaginal vault prolapse due to the higher morbidity associated with this procedure. Prolene suture, and then Prolene mesh was developed based on scientific investigations showing decreased tissue response of a monofilamentous suture compared to multifilamentous sutures such as Gore-Tex. Prolene sutures have been utilized whenever a permanent suture is required in surgery for more than 40 years. Studies also demonstrated that macroporous monofilamentous mesh with pore size greater than 75-100 microns which allowed infiltration of macrophages into the mesh and phagocytosis of any infiltrating bacteria allowed for better ingrowth of tissue and fewer problems with infections and mesh exposure (Amid Langenbecks Arch Chir 1994;379:168, Amid Hernia 1997;1:15).

Using this scientific information as well as the Integral Theory and Hammock Hypothesis of stress continence in the female, Petros, Ulmsten and his team developed the TVT sling. Investigations were performed in animals to find the ideal sling material and surgical technique. The use of macroporous, lightweight polypropylene mesh was found to have minimal tissue response and good ingrowth, as compared to other mesh materials, and was chosen based on these scientific investigations as the mesh material for the TVT sling. Once the sling was developed and tested in the animal model, the TVT sling was then used in women and found to have good results. (Ulmsten Int Urogynecol J 1996;7:81) The procedure was performed under local anesthesia and rigorously standardized. This original cohort of 90 women was followed prospectively over time at regular intervals, with the last follow up conducted at least 17 years after the original procedure to monitor results as well as complications. (Nilsson Int Urogynecol J 2013). The excellent results obtained with minimal complications was replicated by others, following the standardized surgical procedure developed by Ulmsten and colleagues, and based on the highest level of evidence—the randomized controlled trial—has become the world-wide procedure of choice for the surgical treatment of SUI. (Kammerer-Doak Int Urogyn 2016.)

b. Description of the TVT

The TVT sling is composed of monofilamentous Prolene (polypropylene) mesh which is 1.1 cm wide and 45 cm in length, lightweight, about 100 g/m², and macroporous, with pore size about 1,379 microns. The sling is attached to two stainless steel trocars 5

mm in diameter and is covered by a plastic sheath, which is removed after the sling is positioned.

c. Description of the TVT Procedure

With the patient in the dorso-lithotomy position, a Foley catheter is placed to drain the bladder. Local anesthesia is administered 1 cm lateral to the midline just above the pubic bone using a spinal needle placed into the retropubic space for hydrodissection of the bladder from the pubic bone and then brought up through the subcutaneous tissues for the sling trocar exit incisions about 5 mm in length. Attention is then turned vaginally and two clamps are placed just lateral to the midline near the urethral meatus and elevated. The Foley bulb within the bladder is palpated to identify the UVJ to aide in location of the mid-urethra. The mid-urethra is then marked using a sterile marking pen. Placement of the sling at the level of the mid-urethra is important, as 4-D ultrasound studies have demonstrated increased risk of failure when the sling is proximal or distal to the mid-urethra, confirming Petros and Ulmsten's Integral Theory of Female Continence. (Bogusiewicz Prz Menopauzalny 2016;15:123.) Local anesthetic is injected in the vaginal mucosa starting in the midline at the level of the mid-urethra and then also aiming laterally towards the pubic bone. An approximately 1.5 cm incision is then made in the vaginal mucosa at the level of the mid-urethra approximately 1 cm from the urethral meatus using a scalpel and sub-mucosal tunnels are created aiming towards the retropubic space bilaterally using scissors. The catheter guide is then placed and displaced towards the patient's thigh on which the sling is to be placed. The trocar is attached to the re-usable handle, placed into the sub-urethral tunnel on the side to which the catheter guide has been placed, digitally guided into the retro-pubic space, then brought up through the Space of Retzius and out through the abdominal incision. The trocar handle, Foley catheter, and guide are then removed and cystoscopy performed to insure the trocar has not penetrated the bladder. Once bladder and urethral integrity are assured, the cystoscope is removed and the trocar is brought completely through the abdominal incision until the sling mesh covered in the plastic sheath is visualized.

The covered sling is then grasped with a clamp and cut from the trocar. The same procedure is then carried out on the opposite side. The abdominal free ends are then elevated until the sling rests loosely under the urethra. If desired, an intra-operative stress test can be performed and tension adjusted accordingly. In Ulmsten's original reports, the procedure was performed under local anesthetic and sling tension adjusted until stress test was only minimally positive. A clamp is then placed under the urethra as the plastic sheaths covering the mesh are removed abdominally to ensure the mesh is placed under minimal tension. The abdominal incisions are closed, usually with either steri-strips or tissue glue. The vaginal incision is irrigated and the incision closed with a single figure of 8 suture. The bladder is instilled with about 200 ml of fluid for voiding trial in the recovery room. The procedure usually takes about 20-30 minutes to perform, and patients are discharged from the recovery after 1- 2 hours, the majority without a catheter. Patients are instructed to avoid any strenuous activity for 6 weeks, but are able to otherwise return to normal activity usually with several days.

d. Advantages of the TVT Device

The TVT sling is the best studied surgical procedure for SUI with more than 2,000 publications including randomized controlled trials, large registries, and long-term follow up of up to 17 years proving its low risk of complication and high efficacy. (Ogah Cochrane Database Syst Rev 2009, Ford Cochrane Database Syst 2015, Schimpf Am J Obstet Gynecol 2014, Novara EU 2008;53:28.8) Based on this very large body of scientific evidence, mid-urethral slings like the TVT are the safest stress incontinence surgery with least amount of risk and equivalent or superior cure, consistently ranging from 80-90% as compared to other surgeries for SUI. (Ogah Cochrane.) Additionally, success does not appear to decline with time, remaining about 80-90% for objective cure of SUI with 10, 11.5 and 17 year follow up. (Aigmueller Am J Obstet Gynecol 2011;205:496.-e1-5, Olsson Int Urogynecol J 2010;21:679, Svenningsen Int Urogynecol J 2013;24:1271, Serati EU 2012;61:939, and Nilsson Int Urogynecol J 2013). A further benefit of the TVT sling is that unlike the Burch, it can be used to treat all types of SUI, including severe SUI associated with ISD and recurrent SUI. The use of the TVT sling to surgically treat SUI correlates with a significant improvement in QOL as well as sexual function. (Schraffordt Koops BJOG 2006;113:26, AUGS and SUFU Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence.)

Compared to other surgical procedures for SUI, the TVT sling is relatively simple to perform as well as of short duration, usually 20-30 minutes. The original inventors of the sling standardized the procedure and the exact steps of how to perform the procedure have been detailed, allowing the TVT sling to be performed in almost the same manner yielding consistent outcomes. The TVT sling is minimally invasive, requiring minimal tissue dissection and small 5 mm abdominal incisions which can be closed with tissue glue or steri-strips. The vaginal incision is only about 1.5 cm in length and is closed with a single suture. The procedure can be done using local and intravenous anesthesia, and almost all patients are discharged from the recovery room the same day, the majority without a catheter. In women with severe SUI, continence can be tested intra-operatively, and tension of the TVT sling adjusted to achieve continence. If prolonged post-operative urinary retention occurs, which is possible with any type of surgery for SUI, TVT sling transection in the mid-line under the urethra is a short and straightforward procedure which resolves the retention and does not result in recurrent SUI about 75% of the time. This is in contrast to the treatment of urinary retention following the Burch or autologous fascial sling procedures which require extensive and invasive urethrolisis with almost universal recurrence of SUI. Pain after TVT sling is minimal due to the minimally invasive nature of the procedure, with recovery and return to activities of daily living within 1-2 weeks. All surgeries for SUI carry risks from the procedure. The risks for the TVT sling overall are lower than most other surgeries owing to the minimally invasive nature of the procedure without the need for larger incisions with more tissue dissection, abdominal approach, or incisions for the harvesting of autologous fascia. Risks related to TVT sling such as voiding dysfunction, bleeding and injury to bladder and urethra are low, and similar to other surgeries for SUI including the Burch and pubovaginal slings. (Rapoport BCMJ, 2007;49:490, Schimpf Am J Obstet Gynecol 2014, Novara EU 2008;53:288.) Unique to the TVT sling are complications resulting from mesh erosion into the bladder or urethra, and vaginal mesh

exposure, occurring 0.02% and 0.5-2.1%, respectively (Rapoport 2007; Ford AA, Rogerson L, Cody JD, Ogah J, Mid-urethral sling operations for stress urinary incontinence in women, Cochrane Database Syst Rev 7:CD006375, 2015). The TVT sling is associated with a very low likelihood of mesh exposure that may be in part due to its biomechanical property of low stiffness, or ability to deform when placed under force. (Dietz Int Urogynecol J 2003;14:239; Ford Cochrane Review 2015.) The TVT sling is composed of Prolene polypropylene mesh, a Type I macroporous mesh, so classified as the pore size is greater than 75 microns which allows ingrowth and incorporation into the host's tissue as well as macrophages to minimize risk of infection. (Amid Hernia 1997;1:15)

e. Efficacy and Safety of the Device

Mid-urethral slings, including the TVT sling, are considered the new gold standard for the surgical treatment of SUI due to their equivalent or better success and lower overall morbidity (Cox Nat Rev Urol 2013;10:78, AUGS SUFU Position Statement on MUS for SUI, AUA Position Statement on the Use of Vaginal Mesh for SUI, IUGA Position Statement on MUS for SUI, ICS Fact Sheet SUI 2015, RANZCOG and UGSA Position Statement on MUS 2014). The first publications were case series, including the original cohort of women who underwent the TVT sling (Ulmsten Int Urogynecol J Pelvic Floor Dysfunct 1996 7:81). The landmark RCT comparing the former gold standard the Burch, to the TVT sling was published in 2002 demonstrating equivalent success between the two procedures with these results maintained at 5 years follow up (Ward BMJ 325:67 and Ward BJOG 2008;115:226). These findings have been replicated in multiple other RCTs, as well as large cohort studies. (Cochrane Ford 2015 and Ogah 2011, Schimpf 2014, Novara 2008, Tommaselli 2015, Kenton 2015, Schraffordt Koops Am J Obstet Gynecol 2006, Dyrkorn 2010, Tincello J Urol 2011.) Consistently, the TVT sling results in cure of SUI in 80-90% of women with these results maintained with up to 17 years of follow up. (Aigmueller Am J Obstet Gynecol 2011;205:496.-e1-5, Olsson Int Urogynecol J 2010;21:679, Svenningsen Int Urogynecol J 2013;24:1271, Serati EU 2012;61:939, and Nilsson Int Urogynecol J 2013.) The original cohort of women who underwent the TVT sling in 1995 have been evaluated prospectively over the years, with publications at 5, 7, and 11 years, and most recently, at least 17 years after their procedures (Ulmsten Int Urogynecol J 1996, Nilsson Int Urogynecol J 2013). Of the original cohort of 90 who underwent the TVT sling between January 1995 and August 1996, 11 were deceased, 16 women could not be reached, 5 had severe mental impairment, with 58 available for evaluation, representing 78.4% of women who could be assessed. Objective cure was noted in 91%, and subjective cure 79%, with 87.2% reporting that they were either cured or significantly better than before the TVT sling. Of those who considered themselves worse than before the TVT sling, all had urgency incontinence based on the UDI-6. Importantly, only one asymptomatic mesh exposure was noted in a postmenopausal woman not on vaginal estrogen. There was no evidence of shrinkage of the mesh as all women without co-morbidities had normal post-void residuals. Other long-term follow up studies have reported very similar findings.

There are two Cochrane meta-analysis reviews, one which assessed all the RCTs involving studies which compared different types of mid-urethral slings and the other, RCTs which compared mid-urethral slings to other types of SUI surgeries (Ogah 2009, Ford 2015). Minimally invasive mid-urethral slings such as the TVT are as effective as traditional sub-urethral slings and open and laparoscopic Burch colposuspension, but with less operative morbidity (Ogah 2009). The mid-urethral sling, either via the transobturator or retropubic route is equally effective in the short term, with subjective cure ranging from 71-97% and in the long term, 51-88%. Vaginal mesh exposure was about 2%. The transobturator route was associated with more groin pain and repeat surgeries for recurrent SUI, but less bladder perforations noted intra-operatively and post-operative voiding dysfunction than the retropubic TVT sling. (Ford 2015)

A third meta-analysis reported on RCTs that compared sling procedures to the Burch or compared different types of slings. (Schimpf 2014). The Burch and the mid-urethral slings were found to be equally effective in both objective and subjective cure. There was no difference in sexual function, quality of life or groin pain between the Burch and the mid-urethral sling. Mid-urethral slings resulted in less peri-operative complications, pain, urgency/overactive bladder symptoms, and operating and hospital time, but higher vaginal erosion and return to the operating room for urinary retention (0 versus 1.2%), which may be due to the ease with which voiding dysfunction can usually be resolved surgically after the TVT sling compared to the Burch. Compared to the pubovaginal sling, the TVT sling results in better subjective cure, as well as less peri-operative complications and shorter hospital stay, but with higher vaginal perforations during surgical placement.

Differences in complication rates between the TVT sling as compared to other surgeries for SUI from RCTs were assessed in another meta-analysis. (Novara EU 2008) Complication rates were similar for the Burch and TVT sling, but reoperation occurred more frequently after the Burch than the TVT sling. Pubovaginal slings were associated with more hematomas, voiding dysfunction and sling releasing procedures than the TVT sling.

Medium and long-term outcomes after TVT slings has also been assessed in another meta-analysis. (Tommaselli Int Urogynecol J 2015). Subjective, objective and composite cure of SUI with follow up ranging from 5-17 years was 72.7%, 83.2% and 84.1%, respectively for retropubic slings like the TVT sling. The most common complications were de novo OAB (10%) and urinary tract infection (9.3%). Long-term complications included tape erosion in 2.1%, pain in 1.8%, and voiding dysfunction in 5.4%.

Large data registries have demonstrated that complications are low, and comparable to the Burch procedure. (Tamussino 2001, Kuuva 2002, Agostini 2006) The Austrian Registry reported on almost 2,800 TVT sling procedures. (Tamussino 2001.) Bladder perforation at time of placement of the sling is the most common complication, 2.7%, and higher in those with previous SUI surgeries (4.4% versus 2.0%, $P=0.01$). However, bladder perforations recognized cystoscopically intra-operatively and removed have no long-term consequences. Increased bleeding was noted in 2.3%, with 0.7% requiring

re-operation for hematoma or control of bleeding, and small bowel injury in one/2795. The rate of re-operation for voiding dysfunction was 1.0%. The French survey reported on 12,280 TVT sling procedures, with bladder perforation rate of 7.34%, post-operative urinary retention rate of 6.6%, hematoma rate of 0.32% with 14/12,280 requiring surgical procedures for this reason. Incidence of major organ, vascular and bowel injuries were less than 1%. (Agostini 2006.)

Sling revision for voiding dysfunction, or partial removal for vaginal, bladder, or urethral exposure/erosion occurs in up to 0.9% and 1.3% at 1 year, with slight to no increase to 1.3% and 2.5% at 9 years, voiding dysfunction and erosion/exposure, respectively (Welk JAMA Surg 2015, Jonsson Funk AJOG 2013;208:73). This is for all types of mid-urethral slings, not just the TVT. Other studies have reported lower rates for the TVT sling, with 0.6-1.2% undergoing sling revision for voiding dysfunction, and 1-2.9% for exposure/erosion. Nguyen and colleagues reported, based on analysis of 4,142 patients' records, a post-mid-urethral sling procedure reoperation rate of 1.3% for voiding dysfunction or urinary retention, 0.8% for vaginal mesh erosion, and 0.08% for urethral erosion. (Nguyen, Obstet Gynecol 2012.) Variables associated with sling revision/removal include previous SUI surgery and performance of concomitant anterior repair and apical prolapse repair. (Jonsson Funk 2013, Unger 2015.)

Because the TVT sling is retropubic, and is only 1.1 cm wide, very little of the mesh is actually located within the vaginal area. Additionally, the TVT sling is located near the urethral meatus and would not be directly compressed during typical vaginal intercourse. Therefore, dyspareunia, which is a potential complication of any pelvic floor surgery, is rare following retropubic mid-urethral sling procedures like the TVT and is not related to the TVT sling itself. The SGS systematic review from 2014 noted a 0% incidence of dyspareunia with retropubic mid-urethral slings. (Schimpf 2014.) The 2015 Cochrane Review by Ford and Ogah noted that at 2-year follow-up, "rates of superficial and deep dyspareunia were low" with both retropubic and transobturator mid-urethral sling procedures, and that there was actually significant improvement in sexual function from baseline scores during the 2-year follow-up period. (Ford 2015.) Unger's case control study of 3,307 women undergoing sling placement revealed that only 89 (2.7%) underwent sling revision, and only 7.9% of those 89 women (i.e., 7 women) had sling revision for vaginal pain/dyspareunia which was unlikely to have been due to the sling itself. (Unger Int Urogynecol J 2016;27(1):117-22.)

The safety and efficacy of the TVT device has led numerous professional organizations to enthusiastically support polypropylene midurethral slings for the treatment of SUI. ACOG and AUGS's November 2015 Practice Bulletin on Urinary Incontinence in Women notes that "Synthetic midurethral slings demonstrate efficacy that is similar to traditional suburethral fascial slings, open colposuspension, and laparoscopic colposuspension. Compared with suburethral fascial slings, fewer adverse events have been reported with synthetic midurethral slings." It also notes that "[t]here are substantial safety and efficacy data that support the role of synthetic mesh midurethral slings as a primary surgical treatment option for stress urinary incontinence." (ACOG & AUGS Practice Bulletin Summary No. 155, 2015 Nov.) AUGS and SUFU stated in their 2014 Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence

that “[t]he polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for millions of women.” The organizations also noted that “[a] broad evidence base including high quality scientific papers in medical journals in the US and the world supports the use of the MUS as a treatment for SUI. There are greater than 2000 publications in the scientific literature describing the MUS in the treatment of SUI. These studies include the highest level of scientific evidence in the peer reviewed scientific literature.” (AUGS & SUFU Position Statement 2014.) In June 2016, The American Association of Gynecological Laparoscopists (AAGL), ACOG, the National Association for Continence (NAFC), the Society of Gynecologic Surgeons (SGS), and the Women’s Health Foundation (WHF) all signed on as Supporting Organizations for the AUGS/SUFU Position Statement.

The International Urogynecological Association (IUGA) has also issued a Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence, which indicates that IUGA “supports the use of mid-urethral slings (MUS) as one of the options for the surgical management of female stress urinary incontinence (SUI)....” The IUGA Position Statement notes that “[t]here is robust evidence to support the use of MUS from over 2,000 publications making this treatment the most extensively reviewed and evaluated procedure for female stress urinary incontinence now in use.” IUGA noted that it “supports the use of monofilament polypropylene mid-urethral slings for the surgical treatment of female stress urinary incontinence.” (IUGA Position Statement 2014 Jul.) Also, the American Urological Association (AUA) has issued a position statement on the use of vaginal mesh for the surgical treatment of SUI, and has stated that “Suburethral synthetic polypropylene mesh sling placement is the most common surgery currently performed for SUI. Extensive data exist to support the use of synthetic polypropylene mesh suburethral slings for the treatment of female SUI, with minimal morbidity compared with alternative surgeries. Advantages include shorter operative time/anesthetic need, reduced surgical pain, reduced hospitalization, and reduced voiding dysfunction. Mesh-related complications can occur following polypropylene sling placement, but the rate of these complications is acceptably low.”

f. Response to Plaintiffs’ Experts’ Contentions

Mesh has been used in surgery for more than 30 years. The TVT sling has been in use for almost 20 years. There is follow up of women with the TVT sling for up to 17 years (Nilsson 2013) demonstrating that success is maintained relatively stable without significant decline at long term follow up. A very large body of evidence demonstrates the safety and efficacy of the TVT sling. The TVT sling procedure is recognized worldwide as the gold standard for the surgical treatment of SUI based on scientific evidence, including the highest level of evidence, the RCT. (Cochrane Ford 2015 and Ogah 2009, Schimpf 2014, Novara 2008, Tommaselli 2015, Kenton 2015, Schraffordt Koops BJOG Am J Obstet Gynecol 2006, Dyrkorn 2010, Tincello 2011, Cox Nat Rev Urol 2013;10:78, AUGS SUFU Position State on MUS for SUI, AUA Position Statement on the Use of Vaginal Mesh for SUI, IUGA Position Statement on MUS for SUI, ICS Fact Sheet SUI 2015, RANZCOG and UGSA Position Statement on MUS 2014.) If the mesh used in the TVT degraded or was cytotoxic to a clinically significant extent, this

extensive body of scientific evidence would not report the very positive results it does. While there is literature such as the Clavé article discussing polypropylene degradation, there are also studies indicating that the surface cracking seen with explanted polypropylene sutures is not degraded polypropylene but cracks in a protein-based biofilm. (de Tayrac and Letouzey, *Int Urogynecol J* 22:775, 2011; Ong, White, and Thames, *Int. Urogynecol J.* 27(Suppl 1):S19-S149, 2016.) The latter articles are consistent with my experience using polypropylene slings and they are also consistent with the overall body of literature reporting very positive findings with polypropylene mid-urethral sling use. Falconer and colleagues took biopsies of paraurethral connective tissues two years after a TVT procedure and found “practically no tissue reaction at all.” (Falconer, et al., *Int Urogynecol J Pelvic Floor Dysfunct*, 12 Suppl 2:S19-23, 2001.) Monofilament meshes like the TVT mesh have been shown to have significantly higher objective cure rates than multifilament meshes, with fewer mesh erosions. (Ogah, et al., *Neurourology and Urodynamics* 30:284-291, 2011.)

There are no reports in the peer-reviewed journals of any association between TVT mesh and cancer. (AUGS Patient Most Frequently Asked Questions) As Moalli and colleagues noted in 2014, “[o]ver 3 million polypropylene midurethral slings have been sold since the mid 1990s and hundreds of thousands of transvaginal mesh units have been sold in the last 10 years . . . [and] [t]o date, no mesh site cancers have been reported.” (Moalli, et al., *Int Urogynecol J.* 25:573, 2014.) In 2016, Dr. Brian Linder and colleagues at the Mayo Clinic reported finding “no evidence of an association between mesh placement with subsequent local cancer formation” based on an analysis of “a large series of patients undergoing synthetic midurethral sling placement with long-term follow-up” (Linder, et al., *Int Urogynecol J.* 27:1333, 2016.) Complications objectively assessed at short, medium and long-term follow-up in meta-analyses do not reveal any evidence of clinically significant fraying, roping, or curling of the TVT sling mesh. (Schimpf 2014, Novara EU 2008, Tommaselli 2015.) I have not found roping or curling of the mesh to be problematic if the device is implanted in accordance with Ethicon’s instructions for use. Nor have I found fraying or particle loss of the mesh to be a clinically significant problem with the TVT mesh. If particle loss were to occur, the particles lost would be the same Prolene material that has been used in sutures for decades and is known to be very biocompatible.

While TVT mesh exposure does slightly increase with follow-up, from 1.3% at 1 year to 2.5% at 9 years, there is no increase in pain, and no differences in groin pain between the TVT sling and the Burch procedure. (Schimpf 2014.) As the Burch uses just sutures, and there is no difference in pain between the Burch and the TVT sling, mesh cannot be the cause of pain. Sling revision for voiding dysfunction does not increase with time. (Jonsson Funk 2013.) Ultrasound assessment of TVT sling mobility shows no change 2-6 years after placement. (Dietz *AJOG* 2003, Lo *Urology* 2004) One year after TVT sling placement, the mobility of the urethra at rest does not change when assessed prospectively using urethral Q-tip evaluation. (Lukacz *Int Urogynecol J* 2003) These findings as well as stable cure of SUI with long-term follow up effectively prove that there is no significant shrinkage or degradation of the TVT sling over time.

Plaintiffs' experts have contended that laser-cut TVT mesh is excessively stiff, which increases the risk of erosion. The available scientific evidence and data does not support that contention. The literature published prior to 2007 (before laser-cut mesh was available), and from 2007 to the present (when laser-cut mesh was available) does not indicate that there is a clinically significant difference between the two meshes. In my own clinical experience, I did not note any difference between laser and non-laser cut mesh either in the operating room or on post-operative examinations.

Plaintiffs' experts have also contended that the mesh in the TVT device is small-pore, heavyweight mesh, which leads to degradation, contraction/shrinkage, chronic foreign body reaction, chronic inflammation, chronic subclinical infection, and deformation. I disagree with all of these contentions. The mesh in the TVT device is Type I, macroporous mesh. Its pore size is greater than 1,300 microns, far greater than the 75 micron pore size necessary to be considered Type I mesh under the Amid classification discussed above. The pore size is large enough that one can see through the mesh easily and thus is sufficiently large pore to permit tissue ingrowth and permit entry of macrophages to clear bacteria. There is no agreed-upon classification for what constitutes a "lightweight" mesh in the field of urogynecology, but based on the extensive body of scientific literature (including the long-term RCTs, systematic reviews, meta-analyses, and registry studies) discussed above, it is my opinion that the weight of the TVT mesh is optimal. As Ford and colleagues noted in the 2015 Cochrane Review, "Type I mesh has the highest biocompatibility with the least propensity for infection. . . . Macroporous meshes (pore size in excess of 75 um) easily allow macrophages, leukocytes, fibroblasts, blood vessels and collagen to transverse the pores: thus macroporous meshes promote tissue host ingrowth with resultant biocompatibility and low risk of infection (Amid 1997). Monofilament tapes are widely available and now predominate in current clinical practice." (Ford 2015.)

There is no reliable data to support the contention that lighter-weight, larger-pore meshes like Vypro or Ultrapro would perform as well, let alone better than the TVT mesh as a mid-urethral sling material. Ethicon assessed the viability of using Ultrapro mesh in a trans-obturator mid-urethral sling and found that it was not feasible because the mesh stuck to the sheaths in cadaver testing. (Ethicon R&D Memorandum on PA Mesh Assessments for TVTO-PA, ETH.MESH.09922570.) Studies of Ultrapro mesh used to treat incontinence or prolapse show that complications following Ultrapro use are comparable if not higher than those with the use of TVT mesh. (Okulu Scand J Urol 47:217-224, 2013; Milani, et al., Int Urogynecol J 23 (Suppl 2):S43-S244, 2012; Quemener, et al., Eur J Obstet & Gynecol and Reprod Biol. 175:194, 2014.)

g. The Instructions for Use and Surgeon's Resource Monograph

All pelvic surgeries are associated with known risks, which include bleeding, dyspareunia, pain, scarring, fistula formation, inflammation, nerve injury, contraction of tissues, foreign body response to sutures or grafts, erosion or exposure of sutures or grafts, injury to internal organs, and infection. In addition to these risks, all surgeries for incontinence carry a risk of failure to cure SUI, the development of de novo overactive bladder, and urinary retention. Following SUI surgery, the rates of pain including

dyspareunia are quite low, less than 1-2%, and scant evidence exists for a potential link between pelvic pain and minimally invasive SUI surgeries like the TVT sling. (Schimpf 2014.) It is imperative for the surgeon who performs a procedure to know the literature, including evidence-based medicine, and to counsel their patients appropriately about the risks and benefits of any given surgery. It is the responsibility of the surgeon to educate him or herself using available resources which include peer-reviewed journals, continuing medical education, mentorship of colleagues, and the surgeon's own training and experience. The Instructions for Use provided by a manufacturer of a device are solely adjunct materials and are never the only source of information upon which a reasonable surgeon relies. The Instructions for Use specifically warn of adverse reactions such as punctures or lacerations of vessels, nerves, bladder or bowel, transitory local irritation at the wound site, and a transitory foreign body response that may occur and could result in extrusion, erosion, fistula formation, and inflammation. It also warns that the Prolene mesh, like any foreign body, may potentiate an infection. Finally, it warns that improper placement of the sling could result in temporary or permanent lower urinary tract obstruction. It is commonly known among pelvic floor surgeons that any pelvic floor surgery can result in dyspareunia, pain, or persistent/recurrent incontinence. (ABOG Guide to Learning in FPMRS 2012; ACGME Program Requirements for Graduate Medical Education in FPMRS; AUA National Medical Student Curriculum; AUGS Resident Learning Objectives; IUGA Guidelines for Training in FPM-RPS 2010.) It is also commonly known among pelvic floor surgeons that any complication following pelvic floor surgery can be mild, moderate, or severe, and they can be either temporary or permanent. In my opinion, it is not necessary for the TVT Instructions for Use to warn of additional risks that are well-known to be associated with any SUI surgery.

The Surgeon's Resource Monograph was developed by an expert panel of 17 urologists and gynecologists in 2000. This publication, at the behest of Ethicon, Inc. clearly states the importance of adherence to the surgical protocol developed by Ulmsten and colleagues, and that inexperience or deviation from the surgical protocol may increase risk of serious complication. The monograph thoroughly reviews the entire TVT procedure including patient selection, positioning, anesthesia, the steps of the placement of the TVT sling, cystoscopic evaluation, adjustment of sling tension, removal of needles and plastic sheath and closure of the vaginal and abdominal incisions. Antibiotic use as well as patient post-operative care including patient precautions is addressed. The importance of proper training and experience in SUI surgeries prior to use of TVT sling is emphasized in the monograph. Complications, which are expected from a SUI surgery, as well as discussion of possible prevention, assessment and treatment of these complications and use in patients who have had prior pelvic, abdominal and SUI surgery, are thoroughly reviewed in the monograph. The monograph also outlines the studies available in 2000, reporting success rates, dry and improved, and failure rates, as well as complications. In summary, The Surgeon's Resource Monograph is a valuable and thorough publication containing available data regarding the TVT sling. A publication such as this which so thoroughly reviews the entire body of knowledge is not available for any other SUI surgery such as the Burch or pubovaginal sling.

h. TVT Brochures

The TVT Brochure is an educational pamphlet for patients that describes the pathophysiology of SUI and available treatments. The brochure utilizes anatomic drawings as well as written explanations and is a very useful tool when counseling patients about SUI, causes and treatments. Non-surgical options are discussed, as well as the TVT sling. Importantly, the four most common types of UI are described, and that the TVT sling is a treatment option only for SUI. The TVT sling surgical procedure, risks and benefits are reviewed, including the use of mesh and the permanence of the mesh within the body. The brochure is given to patients undergoing consultation for SUI, regardless of ultimate treatment, as it provides a nice overview of the different types of UI, with focus on SUI. It is especially useful for women who decide for surgical treatment due to its thorough review including aftercare.

A handwritten signature in black ink, appearing to read 'Dorothy Kammerer-Doak', written over a horizontal line.

Dated: 1/31/17

Dorothy Kammerer-Doak, M.D.

Dorothy Kammerer-Doak

General Reliance List
in Addition to Materials Referenced in Report

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Production Materials

Document Description [Bates Range]
2001 TVT Surgeon's Monograph
2003 (14 Day Rabbit Study) PSE 02-0579 Stamped Copy March 10, 2003 R&D - Central File: ETH-11280; ETH-11285-297; ETH-11312-315
2006 Mar 3 Flatow memo - CPC-2006-0165 Performance evaluation of TVT PROLENE blue Mesh_ Elongation Properties of Mechanical Cut verses Laser Cut
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DEPO.ETH.MESH.00000367-68 - T-2265 (Prolene Explants - IR Microscopy)
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Email string re - Revised write up of the DeLeval and Waltregny visit
ETH MESH 08476210-6342 - TVT 510(k)
ETH.MESH.00006636 - Interim report mesh explants pelvic floor repair
ETH.MESH.00006796 - Presentation-Stand and Deliver-Pelvic Floor Repair
ETH.MESH.00030098 - Memo from Anthony Powell and Marianne Kaminski to Gynecare Continence Health Sales Team re GYNECARE TVT Physician Training Policy
ETH.MESH.00071794 - Email re: TVT IFUs on tape extrusion, exposure and erosion
ETH.MESH.00074499 - Gynecare Prolift +M-Training Presentation
ETH.MESH.00130934-41 - July 30, 1998 Meeting Notes re TVT
ETH.MESH.00161131-32 - TVT-Innovative Surgical Alternative for the Treatment of Female SUI
ETH.MESH.00167104-110 - 2006 Apr 19 - Laser Cut Mesh for Gynecare TVT- Clinical Expert Report Laser Cut Mesh
ETH.MESH.00211259-60 - Email string re - TVT Exact IFU
ETH.MESH.00220335-36 - 12.2.1999 Memo re: Biocompatibility Risk Assessment for Soft Prolene Mesh.
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ETH.MESH.00260591-592 - Dan Smith Email Plaintiff's Exhibit 180
ETH.MESH.00262015-016 - Dan Smith Email Plaintiffs Exhibit 2067
ETH.MESH.00295355 - 2010 Gynecare TVT Exact Profession Education Slide Deck.
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ETH.MESH.00349228-237 - Ethicon Memo to C. Linsky Re: Cytotoxicity Risk Assessment for the TVT (Ulmsten) Device 8.8.1997
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ETH.MESH.00523617 (2007-4144) - 2007 TVT-Secur Critical Steps
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ETH.MESH.00541379-80 - Memo to File RE: Mesh Draying for TVT Devices 11.18.03
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ETH.MESH.00858175-176 - Mulberry Weekly Meeting MINUTES for 6.3.03
ETH.MESH.00858252-53 - 2004 Memo from London Brown to Dan Smith re Mechanical Cut vs. Laser Cut Mesh Rationale
ETH.MESH.00860142-144 - Email string re-Sample Media TVTO
ETH.MESH.00862176-185 - Prolene Revision History for MS-729-001
ETH.MESH.00862754-757 -6.9.03 Dan Smith Email Re: Double Edged Sword
ETH.MESH.00863391 - T-366 - Dan Smith email - particle loss
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ETH.MESH.01202189 - Stale Kvitle Email regarding Mini Me follow up from our visit May 20, 2009
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ETH.MESH.01220135-45 - Email string re-New Standards for Urethral Slings
ETH.MESH.01221055-58 - Pariente J-L. An Independent biomechanical evaluation of commercially available suburethral slings- 8.5% particle loss.
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ETH.MESH.01238454-56 - Email string re-TVTO length
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ETH.MESH.01808311-318 - Trip Report Michael Tracey
ETH.MESH.01809082-83 - Memo re: VOC on new laser cut TVT mesh
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ETH.MESH.01813975-78 - Email string re-FDA Prep-Plaintiff's Exhibit 460
ETH.MESH.01822361-363 - Dan Smith Email regarding TVT Secur October 18, 2006
ETH.MESH.01822361-62 - Dan Smith Email regarding TVT-Secur leading to less retention
ETH.MESH.02017152-56 - 02.23.2007 Ethicon Expert Meeting: Meshes for Pelvic Floor Repair
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ETH.MESH.02219584 - Scion PA/SUI Treatment Unmet Needs Exploratory Research - Presented January 22, 2010
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Dorothy Kammerer-Doak Materials List**Production Materials**

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ETH.MESH.02330776 (TVTO-384-10-8.12) - TVT-O
ETH.MESH.02340331-335 - TVT IFU (12.22.03 to 02.11.05)
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ETH.MESH.02340829-835 - TVT-O IFU - (01.07.04 to 03.04.05)
ETH.MESH.02341203-13 - TVT Abbrevio IFU
ETH.MESH.02342152-154 - Prolene Mesh IFU (06.18.2010 to present day)
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ETH.MESH.03905472-77 - Email string re-TVT recommendation from Dr. Alex Wang
ETH.MESH.03906976 - Exhibit 2227 - TVOT-04.30.2003-Meeting Report
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ETH.MESH.03910175-77 - Arnaud email re - Soft Prolene
ETH.MESH.03910418-21 - Email string re-Mini TVT - mesh adjustment
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ETH.MESH.03913357-359 - Axel Arnaud Email 5.31.07 Re TVT TVT-O
ETH.MESH.03915380 - Axel Arnaud email re Dr. Lucente-TVT Procedure Improvements-Prevention of Overstretching
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ETH.MESH.03932912 - The History of TVT
ETH.MESH.03941623 - de Leval Email RE: TVT ABBREVO ALERT - French and English Email and English Translation Certification Plaintiff's Exhibit 3619- Perry
ETH.MESH.04044797-800 - TVT Update Jacquetin, B - Klute, C - Stanton, S - Ulmsten, U - Success and Complications
ETH.MESH.04046302 - Powerpoint: TVT and TVT-O Update
ETH.MESH.04048515-520 - Carl Nilsson KOL Interview Project Scion 06.18.08

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ETH.MESH.04050265-267 - Hinoul Letter regarding De Leval Meeting - Pain in Adductor in young Active Patients
ETH.MESH.04079609 - Gynecare TVT Abbrevio Professional Education (Dr. Babcock).
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ETH.MESH.04081301-02 - Memo re - Items need attention
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ETH.MESH.04092868-69 - Email re - 10100080654 and TVT IFUs
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ETH.MESH.04097335-36 - Meng Chen - Medical Assessment for mesh fraying-Tracking 10100054041
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ETH.MESH.04384112 - Biocompatibility Risk Assessment for the TVT-L Device - June 6, 2001
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ETH.MESH.04945231-239 - Email string re-Ultrapro vs Prolene Soft Mesh
ETH.MESH.04945496 - Bernd Klosterhalfen Email Re: Ultrapro vs. Prolene Soft Mesh April 18, 2005
ETH.MESH.05217098-100 - Modified Prolene Mesh Clearance Letter
ETH.MESH.05217103-144 - Modified Prolene Mesh 510(k)
ETH.MESH.05222686-88 - TVT IFU (4th version) 4.7.06-10.7.08
ETH.MESH.05225380-384 - TVT IFU - (09.08.00 to 11.26.03)
ETH.MESH.05315240-65 - 28 Day Rat Study
ETH.MESH.05316775-812 - Report, PSE Accession NO. 02-0579-T-2133
ETH.MESH.05320909 (2008-135)(38 slides summit) - 2008 TVT-Secur
ETH.MESH.05337217-220 - Email string, top one from D. Miller to J. Paradise, et al
ETH.MESH.05347751-762 - Email string re Investigator-initiated studied policy
ETH.MESH.05479411 - The (clinical) argument of lightweight mesh in abdominal surgery
ETH.MESH.05479535
ETH.MESH.05529274-75 - Gynecare TVT Tension Free Support for Incontinence
ETH.MESH.05529653 - Email string re - Problem statements for TVT brainstorming meeting
ETH.MESH.05572912-913 - Ethicon Professional Education Description
ETH.MESH.05588123-126 - Stephen Wohlert Email - AW: How inert is polypropylene? July 9, 2007
ETH.MESH.05644163-171 - Pelvic Floor Repair-Surgeon's Feed-back on Mesh Concept
ETH.MESH.05795421-508 - Gynecare TVT Tension-Free Support for Incontinence: Professional Education Slides.
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ETH.MESH.05799233-39 - TVT Exact IFU
ETH.MESH.05916450 - Chronic Pain-Prevention, Future - Bioengineers point of view-D21929 (Powerpoint)
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ETH.MESH.05958248 - Surgeons Resource Monograph
ETH.MESH.05998805-806 - Piet Hinoul Email RE: ALERTE TVT ABBREVO - Plaintiff's Exhibit 3837
ETH.MESH.05998835-836 - Piet Hinoul Email Re: ALERTE TVT ABBREVO
ETH.MESH.06592243 - 09.14.2012 Email from Carl Nilsson to Laura Angelini
ETH.MESH.06695438 - Justification for Utilizing the Elasticity Test as the Elongation Requirements on TVT LCM

Dorothy Kammerer-Doak Materials List**Production Materials**

ETH.MESH.06881576-80 - Email string re-TVTO
ETH.MESH.06887138-40 - Waltregny email written on behalf of Professor de Levalre IFU .
ETH.MESH.06887241-244 - David Waltregny email 7.16.04 re TVT-O
ETH.MESH.06887244 - 07.16.04 David Waltregny email to Dan Smith re: TVT-O.
ETH.MESH.06887245-246 - Dan Smith Email 7.15.04
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ETH.MESH.06894461 - Klinge U, et al. Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model. Journal of Surgical Research 103, 208-214 (2002).
ETH.MESH.06917699-704 - Form For Customer Requirements Specification (CRS) For Project TVT-O PA
ETH.MESH.06923868-871 - TVTO-PA Clinical Strategy - 8.21.13 Exhibit A.M. Mitchell T-2177
ETH.MESH.06927231-235 - Email string re-Scion PA commercail recommendation
ETH.MESH.07192929 - Investigating Mesh Erosion in Pelvic Floor Repair Powerpoint
ETH.MESH.07226481 - Ethicon (Burkley) response to Clave paper re degradation
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ETH.MESH.07318311-313 - de Leval Email Re: TVT ABBREVO ALERT - French and English Email and English Translation Certification - Plaintiff's Exhibit 3613
ETH.MESH.07383730-31 - Email string re-Ultrapro mesh information-identical mesh to Prolift +M
ETH.MESH.07387254-257 - Email RE: August Status Report - Gynecare marketing [11.6.13 Exhibit T-3365]
ETH.MESH.07455220 - 3.6.2012 Response to email from C. Huntington RE: inertness of polypropylene mesh
ETH.MESH.08003181-96 - TVT Patient Brochure
ETH.MESH.08003231-46 - TVT Patient Brochure
ETH.MESH.08003279-94 - TVT Patient Brochure
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ETH.MESH.08156958 - 2002 Gynecare TVT Tension-Free Support for Incontinence: Advanced Users Forum for the Experienced Clinician.
ETH.MESH.08165497-99 - Meeting Minutes-TVT Development Team Meeting
ETH.MESH.08299913-917 - Nilsson C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J 2013; 24(8): 1265-9 [9.11.13 Exhibit T-1271]
ETH.MESH.08307644-45 - 4.05.2013 - Email from P. Hinoul to G. Callen re: RCT data (with attachments).
ETH.MESH.08311158 - Results - 175 Patients Enrolled and Randomized
ETH.MESH.08315779 - Clinical Expert report-09.25.2012
ETH.MESH.08319128-129 - Ethicon DM Sales Rep Do's and Don'ts [7.11.13 Exhibit T 791]
ETH.MESH.08334244-45 - Email string re: Photographs of LCM vs MCM with powerpoint attachment
ETH.MESH.08476210 - Fax from FDA requesting changes to labeling
ETH.MESH.08476217-24 - Fax from FDA requesting changes to labelling
ETH.MESH.08568006-12 - Feola A, et al. Stress Shielding-The Impact of Mesh Stiffness on Vaginal Function. Female Pelvic Medicine & Reconstructive Surgery, Vol 17, No 5, Suppl 2, Sept/Oct 2011.
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ETH.MESH.09264945-46 - Prolene Mesh Re-Design Project

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ETH.MESH.09306898-910 - Incontinence - Plaintiffs Exhibit 4164-R
ETH.MESH.09625731-737 -NDA 16-374 4.16.69
ETH.MESH.09629447-448 - Letter to Dr. Grigsby RE: Prolene Polypropylene Suture, U.S.P., NDA #16-374
ETH.MESH.09630649 - 4.26.1973 FDA Letter RE: NDA 16-374
ETH.MESH.09630649 - FDA Prolene NDA Supplement with Transitory language
ETH.MESH.09634081 - Section 6 - Info concerning the quantity of drug distributed
ETH.MESH.09634318 - Prolene Package Insert
ETH.MESH.09634664-77 - 1990 FDA reclassification letter
ETH.MESH.09634664-88 - July 5, 1990 FDA Order
ETH.MESH.09656792
ETH.MESH.09656795
ETH.MESH.09744840-45 - TVT Patient Brochure 2.14.13
ETH.MESH.09744858-63 - TVT Patient Brochure
ETH.MESH.09744866-67 - TVT Abbrevio
ETH.MESH.09746948-998 - License and Supply Agreement [Rosenzweig Exhibit 21 - 12.22.15]
ETH.MESH.09747038-097 - Medscand Agreement
ETH.MESH.09747337-369 - Asset Purchase Agreement
ETH.MESH.09888187-223 - Seven Year Data for Ten Year Prolene Study - Plaintiff's Exhibit 4102
ETH.MESH.09922570 - MO PA (TOPA) R&D Memo on PA Mesh Assessments for MO-PA
ETH.MESH.09922570-578 - R&D Memorandum of PA Mesh Assessments for TVTO-PA Revision 1
ETH.MESH.10027307-28 - Surgeon's Resource Monograph
ETH.MESH.10150872 - Supplier Chart
ETH.MESH.10216874-875 - Email string RE: AUGS lecture-content of discussions
ETH.MESH.10281860 - Clinical Expertise TVT Midurethral sling: market Update Prof Ed Slide Deck
ETH.MESH.10575607-13 - Prolene Mesh - Biological Evaluation in Rabbits
ETH.MESH.11335728
ETH.MESH.11336474-87 - Ten Year In Vivo Suture Study Scanning Electron Microscopy-5 Year Report - Plaintiff's Exhibit 4111
ETH.MESH.12009027-35 - Gynemesh II-New Mesh Design
ETH.MESH.12831391-393 - September 30, 1987 Letter to Dr. Melveger
ETH.MESH.12831391-404 - IR Microscopy of Explanted Prolene received from Prof. R. Guidoin.
ETH.MESH.12831391-92 - P4128 - IR Microscopy of Explanted Prolene received from Prof. R. Guidoin.
ETH.MESH.12831405 - June 15, 1982 Memo to Dr. Melveger RE: Crack Depth in Explanted Porlene, Polypropylene Sutures
ETH.MESH.14369950 - ISO 14971 - Medical Devices - Application of risk management to medical devices
ETH.MESH.16357664-68 - Therapeutic Products Directorate
ETH.MESH.16416002-004 - Helen Kahlson Email Re: Conversion to Laser Cut TVT
ETH.MESH.17636681-84 - Identification of Issue - Problem Statement-Description
ETH.MESH.17776990-7011 - Biocompatibility Risk Assessment Report for TVT
ETH.MESH.22617620-770 - Letter to FDA re K974098 TVT
ETH.MESH.22625140-45 - MDD CAPA # CAPA-003474
ETH.MESH.22631022-2029 - TVT - Response to Section 39 Request
ETH.MESH.22634691-92 - Email re - Physician and Patient Labeling Updates to Ethicon Urogynecologic Surgical Mesh - D-8

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ETH.MESH.22865906-21 & ETH.MESH.24255174-89 - Email re - Ethicon 510(k) amendments for labeling changes - D-7
ETH.MESH01816988-990
ETH.MESH02017152 - Ethicon Expert Meeting-Meshes for the Pelvic Floor Repair
ETH.MESH-08476311 - Cytotoxicity assessment of Ulstem sling
Guidoin R and Chakfe N. Aneurysmal Deterioration of Arterial Substitutes.
Gynecare TVT IFU changes redlined, D-6, 1-20
Gynecology Solutions
Heniford DVD Transcription
HMESH_ETH_11642462 - Franchise Regulatory Labeling Guidance - Summary of Changes
Johnson & Johnson - Our Credo [8.9.13 A.M. Mitchell Exhibit T-3134]
June, 2009 Klosterhalfen intermediate report on explanted mesh
Kaufman MR. Contemporary role of autologous fascial bladder neck slings: a urology perspective. Controversies in Female Pelvic Reconstruction, 2012, 39(3): 317-323.
Klinge Presentation PVDF: a new alternative? Meeting o Hernia Experts Exhibit P-1944
Letter to Editor re: Ostergard & Sternschuss 2012 Post-implantation alterations of polypropylene in the human.
Librojo updated TVT Declaration (10-23-15) [12 pages]
McCabe email re - Sheath Sales Tool - 464
Miller JM, et al. Clinical Evaluation of Monofilament Polypropylene Suture. Am. Surgeon 33 - 666-70. (1967)
MSDS-Marlex Polypropylenes
Our Credo[8.9.13 A.M. Mitchell Exhibit T-3134
P4117 - Figure 7: Sample 13159, Lot #3405405 (Photograph)
P4118 - Figure 26: J8041-13675 (Photograph)
P4122 - SEM Figure 183: Sample J7959 13409 (Photographs)
Payments to Medscand [9.16.13 Exhibit T-3192]
Payments to Medscand by J&J [9.16.13 Exhibit T-3183]
Payments to Ulmsten as Consultant [9.16.13 Exhibit T-3204]
Powerpoint - LCM Project: Photographs Comparing Laser Cut Mesh vs. Mechanical Cut Mesh
Prolene Resin Manufacturing Specifications 1.23.03 [DX23600-R.1-3]
Published clinical data and RCTs - Ethicon.com - 4204-C
Seven Year Dog Study - T-2263
T-2262 - Deposition Subject Matter Thomas Barbolt Deposition 1.8.14
Te Linde's Operative Gynecology - Plaintiff's Exhibit 3958
T-Pro (Thunder) Pipeline Leadership Team (PLT)
TVT Abbrevo IFU - 01.2015
TVT Exact IFU - 01.2015
TVT IFU - 01.2015
TVT IFU (7th version) 2015 - Present - from Ethicon website.
TVT Patient Brochure - 2015
TVT-O la bandelette trans-obturatrice (Photograph)
TVT-Obturator - 01.2015
TVT-Obturator IFU - 01.2015

Dorothy Kammerer-Doak Materials List**Company Witness Depositions**

Deponent [Date of Deposition]
Arnaud, Axel - 07.19.13 Deposition Testimony
Arnaud, Axel - 09.25.13 Deposition Testimony
Barbolt, Thomas - 01.08.2014 Deposition Testimony
Barbolt, Thomas - 10.09.2012 Deposition Testimony
Beath, Catherine - 07.11.13 Deposition Testimony
Chen, Meng - 10.29.13 Deposition Testimony
Chen, Meng - 10.30.13 Deposition Testimony
Hart, James - 09.18.13 Deposition Testimony
Hinoul, Piet - 01.13.2014 Deposition Testimony
Hinoul, Piet - 01.14.14 Deposition Testimony
Hinoul, Piet - 01.15.2014 Deposition Testimony
Hinoul, Piet - 02.01.16 Carlino Testimony Played in Court
Hinoul, Piet - 04.05.12 Deposition Testimony
Hinoul, Piet - 06.26.2013 Deposition Testimony
Hinoul, Piet - 06.27.13 Deposition Testimony
Hinoul, Piet - 09.18.12 Deposition Testimony
Holste, Joerg - 12.15.12 Deposition Testimony
Isenberg, Richard - 11.05.13 Deposition Testimony
Isenberg, Richard - 11.06.13 Deposition Testimony
Kirkemo, Aaron - 01.06.14 Deposition Testimony
Kirkemo, Aaron - 01.07.14 Deposition Testimony
Nager, Charles - 06.10.14 Deposition Testimony
Owens, Charlotte - 06.19.13 Deposition Testimony
Owens, Charlotte - 06.20.13 Deposition Testimony
Robinson, David - 07.24.13 Deposition Testimony
Robinson, David - 07.25.13 Deposition Testimony
Robinson, David - 09.11.13 Deposition Testimony
Weisberg, Martin - 02.03.16 Carlino Testimony Played in Court
Weisberg, Martin - 05.24.12 Deposition Testimony
Weisberg, Martin - 05.31.2013 Deposition Testimony
Weisberg, Martin - 08.09.13 Deposition Testimony
Weisberg, Martin - 11.12.15 Deposition Testimony
Weisberg, Martin - 11.13.15 Deposition Testimony

Other Materials

10/20/08 FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence.
2007 NIHCE Interventional procedure overview of single-incision sub-urethral short tape insertion for stress urinary incontinence in women.
2011 AUA Position Statement on the Use of Vaginal Mesh for SUI
2012 ABOG Guide to Learning in Female Pelvic Medicine and Reconstructive Surgery
2012 Update - AUA SUI Guidelines- Appendices A11 and A16 (re Complications)
2013 Oct. AUA Position Statement on the Use of Vaginal mesh for the Surgical Treatment of SUI
2013 Sept. NICE 171 Guideline - The management of urinary incontinence in women
2014 Jan - AUGS-SUFU MUS Position Statement APPROVED 1 3 2014
2014 July - IUGA Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence
2014 Mar 12 - AUGS SUFU Provider FAQs MUS for SUI
2014 RANZOG and UGSA Position Statement
2015 ACOG, AUGS Practice Bulletin Summary of 155 - Urinary Incontinence in Women (replaces 63 from June 2005)
2015 AUA. A Monograph from the Urology Care Foundation. SUI. Update 2015
2015 Mar EAU Guidelines on Urinary Incontinence
2016 AUGS (eposter) Serious adverse events with transvaginal mesh are rare.
2016 AUGS, SUFU, ACOG, SGS, AAGL, NAFC,WHF, Position Statement - Mesh Midurethral Slings for Stress Urinary Incontinence
2017 AUA/SUFU Guideline - Surgical Treatment of Female Stress Urinary Incontinence
2018 (Feb) AUGS, SUFU, ACOG, IUGA, SGS, AAGL Position Statement re: Midurethral Slings
2018 RANZCOG Position Statement on SUI and POP
21 CFR 801.109(c) - Device Labeling
21 CFR 860.7
7/13/11 FDA: Surgical Placement of Mesh to Repair Pelvic Organ Prolapse Poses Risks.
A Comparative Transobturator Sling Matrix - Boston Scientific www.pelvic-floor-institute.com 2012
A Summary of the evidence on the benefits and risks of vaginal mesh implants. October 28, 2014
ABOG and ABU - 2012 Guide to Learning in FPMR
ACGME Program Requirements
ACGME Program Requirements for Graduate FPMRS, July 1, 2014.
ACGME Program Requirements for Graduate Medical Education in FPMRS
ACOG Chronic Pelvic Pain
ACOG Frequently Asked Questions - When Sex Is Painful
ACOG Surgery for Stress Urinary Incontinence FAQ
ACOG, AUGS Committee Opinion No. 694 Management of Mesh and Graft Complications in Gynecologic Surgery.Female Pelvic Med Reconstr Surg 2017.
ACOG, AUGS Practice Bulletin 155 (replaces 63 from 2005) Urinary Incontinence in Women.
ACOG, AUGS Practice Bulletin Summary of 155 (replaces 63 from 2005) Urinary Incontinence in Women.
AUA Guideline for the Surgical Management of Female Stress Urinary Incontinence Update (2009)
AUA National Medical Student Curriculum Urinary Incontinence
AUA National Medical Student Curriculum, updated August 2012
AUGS SUFU Frequently Asked Questions by Patients Mid-urethral Slings for Stress Urinary Incontinence
AUGS Blogs Organizations Lend their Support to Mid-urethral Slings
AUGS FAQs-Mid-urethral Slings for SUI-DX23540

Other Materials

AUGS Position Statement on Restrictions of Surgical Options for Pelvic Floor Disorders
AUGS President's Perspective: Organizations Lend their Support to Mid-urethral Slings. June 23, 2016.
AUGS Resident Learning Objectives
AUGS SUFU Frequently Asked Questions by Patients MUS for SUI
AUGS SUFU Frequently Asked Questions by Providers MUS for SUI
AUGS SUFU Position Statement on MUS for SUI
AUGS-SUFU MUS Position Statement updated June 2016
Brief Summary of the Gastroenterology and Urology Panel of the Medical Devices Advisory Committee Meeting - 02/26/2016
Code of Federal Regulations Title 21, as of 4/1/15. 21CFR801.109
Committee Opinion No. 694: Management of Mesh and Graft Complications in Gynecologic Surgery. Obstet Gynecol. 2017 Apr;129(4):e102-e108. Committee Opinion No. 694 Summary: Management of Mesh and Graft Complications in Gynecologic Surgery. Obstet Gynecol. 2017 Apr;129(4):773-774.
Deposition Subject Matter-Design and Development of Mesh Products
Device Labeling Guidance
EAU Guidelines on Urinary Incontinence. Urinary Incontinence - partial update March 2015
EU Commission Fact Sheet - (based on 2015 SCENIHR Report) The safety of surgical meshes used in Urogynecological surgery.
EU Commission Fact Sheet 2015
Evidence Pyramid
FDA Considerations about Surgical Mesh for SUI
FDA Considerations about Surgical Mesh for SUI [03.27.2013].
FDA Device Labeling Guidance #G91-1 March 1991
FDA Executive Summary - Reclassification of Urogynecologic Surgical Mesh Instrumentation; Gastroenterology-Urology Medical Devices Advisory Committee Panel 02/26/2016
FDA Executive Summary: Surgical mesh for treatment of women with POP and SUI [09.08.2011]
FDA Implants and Prosthetics
FDA News Release: Surgical Placement of mesh to repair pelvic organ prolapse poses risk [07.13.2011].
FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of POP and SUI. Issued: 10.20.2008.
FDA Questions (Reclassification of Urogynecologic Surgical Mesh Instrumentation), February 26, 2016.
FDA Questions: Reclassification of the Urogynecologic Surgical Mesh Instrumentation.
FDA Reclassification of Urogynecologic Surgical Mesh Instrumentation, February 26, 2016.
FDA Statement re Considerations about Surgical Mesh for SUI; 2013 Mar 27
FDA Stress Urinary Incontinence
Female SUI Procedures
Final Appraisal Determination Tension Free Vaginal Tape Gynecare TVT for Stress Incontinence. National Institute for Clinical Excellence (2003)
Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee: Medical Devices Classification/Reclassification. February 26, 2016
ICS Fact Sheet 2015
IUGA Guidelines for training in FPMRPS; Updated 2010
IUGA Interstitial Cystitis and Painful Bladder Syndrome (2011)

Other Materials

IUGA Low-Dose Vaginal Estrogen Therapy (2011)
IUGA Mid-urethral sling (MUS) procedures for stress incontinence (2011)
IUGA Position Statement on MUS for SUI (2014)
Oxford Levels of Evidence Pyramid for Practitioners_from Oxford website
Oxford Levels of Evidence; www.cebi.ox.ac.uk/fileadmin/_processed_/csm_Evidence_pyramid_bluef5c85529a0.jpg
Pence Direct Slides
RANZCOG Position statement on midurethral slings (May 2017)
RCT Pyramid
Slide re Dr. Hinoul - Ethicon Medical Director - Rosenzweig 64
The Kings Health Questionnaire

Dorothy Kammerer-Doak Materials List

MDL Wave Cases

Depositions
Blaivas, Jerry, M.D. (TVT General) 9.17.2015
Blaivas, Jerry, M.D. (TVT General) 9.24.2015
Elliott, Daniel S, M.D. (TVT General) 9.26.2015
Iakovlev, Vladimir, M.D. (TVT General) - 09.11.2015
Margolis, Michael (Carlino TVT) 11.21.2015
Margolis, Michael (Cederberg TVT, TVT-S) - 04.29.2017
Margolis, Michael (Lewis TVT) 11.25.2013
Ostergard, Donald (Wave 1 General) 03.09.2016
Rosenzweig, Bruce (Carlino TVT) 1.14.2016
Rosenzweig, Bruce (Carlino TVT) 12.22.2015
Rosenzweig, Bruce (Huskey/Edwards TVT-O) - 03.24.2014
Rosenzweig, Bruce (Lewis TVT) 11.04.2013
Rosenzweig, Bruce (Ramirez TVT-O) - 03.31.2016
Rosenzweig, Bruce (Ramirez TVT-O) - 10.11.2014
Rosenzweig, Bruce (Susan Smith TVT-O) - 08.31.2016
Rosenzweig, Bruce (TVT General) 9.22.2015
Rosenzweig, Bruce(Carlino TVT) 1.13.2016
Expert Reports
Blaivas, Jerry (TVT General) - 01.17.2017
Elliott, Daniel (TVT General) - 02.01.2016
Guelcher, Scott (Wave 5 General) - Received 07.27.2016
Iakovlev, Vladimir (General) - 01.29.2016
Jordi, Howard (General) - 02.01.2016
Klinge, Uwe (TVT General) - 11.16.2015
Margolis, Michael (TVT General) - 02.01.2016
Margolis, Michael (TVT General) - 05.21.2017
Mays, Jimmy (General) - 05.22.2017
Michaels, Paul (General) - 07.01.2016
Pence, Peggy (General TVT) - 10.14.2013
Pence, Peggy (Notice of Adoption of Prior Reports) - 02.01.2016
Pence, Peggy (Supplemental General TVT & TVT-O) - 03.02.2016
Pence, Peggy (Supplemental General TVT-O) - 04.24.2015
Plaintiff expert reports and materials cited in Wave general reports of Blaivas, Elliott, Margolis and Rosenzweig
Plaintiffs' Wave general expert reports and materials cited
Rosenzweig, Bruce (TVT General) - 05.22.2017
Rosenzweig, Bruce (TVT General) - 06.09.2014
Rosenzweig, Bruce (TVT General) - 08.24.2015
Rosenzweig, Bruce (TVT General) - 10.14.2013
Rosenzweig, Bruce (TVT Supplemental General) - 01.06.2017
Rosenzweig, Bruce (TVT, TVT-O Notice of Adoption of Prior Reports) - 12.15.2015
Rosenzweig, Bruce (TVT-O General) - 02.21.2014
Rosenzweig, Bruce (TVT-O General) - 04.24.2015
Veronikis, Dionysios (TVT General) - 1.25.2016
Wilson, Anne (TVT General) - 01.25.2016

CURRICULUM VITAE
2018

Name Dorothy Kammerer-Doak, M.D.

Professional Address: Women's Pelvic Specialty Care P.C.
4705 Montgomery Blvd NE Suite 201
Albuquerque, NM 87109
Phone (505) 888-0443
FAX (505) 888-1398

Licensure: New Mexico 1993, License Number #93-295
California 1994, License Number #G068436 (Not Active)
Arizona 1992, License Number #20803 (Not Active)

Certifications: American Board of Obstetricians and Gynecologists 1996
Board Certified November 1995
American Board of Obstetricians and Gynecologist, Subspecialty
Certification, Female Pelvic Medicine and Reconstructive Surgery,
Certified June 2013

Educational History: Fellowship: Advanced Gynecological Surgery
Mayo Clinic, Scottsdale
Scottsdale, AZ
1992-1993

Residency: Obstetrics and Gynecology
University of California Irvine Medical Center
Orange, CA
1988-1992

Medical School (s):
University of California Irvine School of Medicine 1984-1985
University of California Davis School of Medicine
Davis, CA
Medical Degree
1985-1988

Undergraduate Bachelor of Arts, Biology
Minor, Sociology
University of California, San Diego
La Jolla, CA
1979-1983 Magna Cum Laude

Employment History:

Women's Pelvic Specialty Care
Private Practice, Gynecology, Urogynecology & Pelvic Floor Disorders
Clinical Associate Professor, University of New Mexico Hospital
Albuquerque, New Mexico
January 2009-current

ABQ Health Partners (Lovelace Health Systems)
Obstetrics and Gynecology
Urogynecology and Pelvic Floor Disorders
Clinical Associate Professor, University of New Mexico Hospital
Albuquerque, New Mexico
July 1999-December 2008

Associate Professor, Obstetrics and Gynecology
University of New Mexico Hospital
Albuquerque, New Mexico
1993 to 1999

**Professional recognition,
honors, etc:**

Outstanding Volunteer Faculty Teaching Award 2007-2008

Professional General Clinical Research Center Scholars Program
1997-1999

Berlex Foundation Junior Faculty Development Award, 1996

Robert Willson Best Faculty Teacher Award, 1993-1994

Medical School Michael G. Corbett Award for Excellence in
Critical Care Medicine. 1988

Undergraduate University Scholarship UC San Diego. 1979-1983

Education Abroad Scholarship, University of
Andrews, Scotland. 1981-1982

Professional Societies:

Fellow of The American College of Obstetricians and Gynecologists
American Medical Women's Association (Past)
Associate Fellow American College of Surgeons (Past)
Greater Albuquerque Medical Association
American Urogynecologic Society
Society for Gynecologic Surgeons
International Urogynecology Association

**Extramural
Professional
Activities:**

International Surgical Missions trip, Biri Islands, Philippines, February 2018
Volunteer Visiting faculty, International Urogynecology Association Fellowship
Training Program, Ghana, Africa, July 2017
Member International Urogynecology Association Research & Development
Committee 2007-2016
Chair 2011-2015
Speaker Bureau, Pfizer, "Toviaz" 2010—2011
Surgical Services Committee, Lovelace Health Systems, 1999-2004
Journal Reviewer, Obstetrics and Gynecology, 1998-present
Journal Reviewer, International Journal Urogynecology 2002-present
Surgical Services Committee, University of New Mexico Hospital, 1993 - 1999
Clinical Research Center Advisory Committee, University of New Mexico Hospital
May 1996 – 1999
Gynecological Statistics Committee, Department of Obstetrics & Gynecology
University of New Mexico 1993 – 1995
Research Committee, Department of Obstetrics and Gynecology, 1998-1999
Faculty Senator, The University of New Mexico Faculty Senate, 1997 - 1999
Membership Committee, Central Association of Obstetrics and Gynecology, 1998-2000
Director Urogynecology and Pelvic Floor Disorders Fellowship September 1997 - 1999
Interim Director of Obstetrics and Gynecology Services, Kirtland Air Force Base 5/97 -
8/97

Invited Lectures:

Mayo Clinic Scottsdale (1992-1993) :

7/92	"Chronic Pelvic Pain" Presented at: Gynecologic Lecture Series OB/GYN Grand Rounds 12/92
8/92	"Hormonal Therapy in Women With History of Gynecologic Malignancy" Presented at: Gynecologic Lecture Series
9/92	"Germ Cell Tumors" Presented at: Gynecologic Lecture Series
10/92	"Mild Endometriosis: Diagnosis and Treatment Strategies" Presented at: Gynecologic Lecture Series
11/92	"Urodynamic Investigation: Who Needs It?"

Presented at: Gynecologic Lecture Series

12/92 “Flow Cytometry in Gynecologic Oncology”
Presented at: Gynecologic Lecture Series

1/93 “Anal Incontinence: Diagnosis and Treatment Strategies”
Presented at: Gynecologic Lecture Series

2/93 “Vesicovaginal Fistulas: Diagnosis, Prevention and
Treatment”
Presented at: Gynecologic Lecture Series

3/93 “Intraoperative Complication: Prevention and Management
Strategies”
Presented at: Gynecologic Lecture Series

4/93 “Tamoxifen: Review of Gynecologic Effects”
Presented at: Gynecologic Lecture Series

5/93 “Ovarian Cancer Screening”
Presented at: Mayo Clinic Scottsdale CPC

6/93 “Medical Management of Urinary Incontinence”
Presented at: Gynecologic Lecture Series

UNIVERSITY OF NEW MEXICO (1993 - 1999)

1/94 “Intraoperative Complications of Gynecologic Surgery”
Presented AT: OB/GYN Grand Rounds, UNMH

2/94 “Hormone Replacement Therapy in Patients With History
of Breast Cancer”
Presented at: 27th Annual OB/GYN Post Graduate
Conference, UNMH

6/94 “Pelvic Anatomy, Physiology and Neurology of the Lower
Urinary Tract”
Presented at: OB/GYN Grand Rounds, UNMH

6/94 “Urodynamic Evaluation”
Presented at: OB/GYN Grand Rounds, UNMH

2/95 “Laparoscopic Management of Adnexal Masses”
Presented at: 28th Annual OB/GYN Post Graduate
Conference, UNMH

- 2/95 “Vesicovaginal Fistula: Prevention and Management:
Presented at: The New Mexico Section of ACOG,
Santa Fe, New Mexico
- 3/95 “Anal Incontinence:
Presented at: OB/GYN Grand Rounds, UNMH
- 4/95 “Initiation of Hormone Replacement Therapy”
Presented at: Department of Internal Medicine,
Noontime Conference, UNMH
- 12/95 “An Overview of Urogynecology”
Presented at: OB/GYN Grand Rounds
- 1/96 “Practical Urogynecology: An Approach for the General
Practitioner”
Presented at: 7th annual Navajo Area IHS
Obstetrical/Pediatric Midwinter Conference, Telluride, CO
- 2/96 “Fecal Incontinence: An Introduction.”
Presented at: 29th Annual OB/GYN Post Graduate
Conference, UNMH
- 5/96 “Introduction to Clinical Epidemiology”
Presented at: OB/GYN Grand Rounds, UNMH
- 7/96 “Practical Urogynecology: An Approach for the
General Practitioner”
Presented at: Grand Rounds, St. Vincent’s
Hospital, Santa Fe NM (UNMH Out Reach)
- 11/97 “Overview of Urinary Incontinence in the Female”
Presented at: Rocky Mountain Region/WOCN Conference
Albuquerque, NM
- 1/98 “Interstitial Cystitis: The Painful Bladder Syndrome”
Presented at: Navajo Area Midwinter Conference on Women’s Health
Midwinter Conference, Telluride, CO
- 3/98 “Randomized Comparisons of Burch Urethropexy and Kelly-Kennedy Anterior
Colporrhaphy”
Presented at: The 7th Annual Symposium on Urogynecologic and Pelvic
Reconstructive Surgery Conference,
Mayo Clinic, Scottsdale, Arizona
- 3/98 “Osteomyelitis Following Pelvic Surgery”
Presented at: The 7th Annual Symposium on Urogynecologic and Pelvic
-

Reconstructive Surgery Conference,
Mayo Clinic, Scottsdale, Arizona

- 5/98 “Interstitial Cystitis: The Chronic Pain Syndrome of the Bladder”
Presented at: OB/GYN Grand Rounds, Carolinas HealthCare System
Charlotte, NC
- 5/98 “Osteomyelitis Following Pelvic Surgery”
Presented at: OB/GYN Grand Rounds, UNMH
- 2/99 “An Overview Fecal Incontinence in the Female”
Presented at: Navajo Area Midwinter Conference on Women’s Health
Midwinter Conference, Telluride, CO
- 2/99 “A Prospective Cohort Study Following Primary Repair of Obstetrical and
Sphincter Laceration”, Society of Gynecologic Surgeons Twenty-Fifth Annual
Scientific Session ,
San Diego, California
- 3/99 “Epidemiology & Complications of Hysterectomy”, “Burch Urethropexy Versus
Sling Versus Anterior Colporrhaphy”, “Irritative Voiding Symptoms/Interstitial
Cystitis” Presented at: The 8th Annual Urogynecology & Disorders of the Female
Pelvic Floor Conference,
Mayo Clinic, Scottsdale, Arizona
- 4/99 “The Practical Approach to Urogynecology”
Presented at Family Practice Grand Rounds, UNMH

LOVELACE HEALTH SYSTEMS/ABQ Health Partners (1999 - 2008)

- 10/99 “Fecal Incontinence: An Overview in the Female”
Presented at: Lovelace Obstetrics and Gynecology Departmental Grand Rounds
- 2/00 “Medical and Surgical Management of Urinary Incontinence in the Female”
Presented at: 33rd Annual OB/GYN Post Graduate
Conference, UNMH
- 3/00 “The Posterior Compartment”
Presented at: Lovelace Obstetrics and Gynecology Departmental Grand Rounds
- 5/01 “Obstetrical Anal Sphincter Lacerations: An Evidence Based Review”
Presented at: Annual Meeting of the American College of Obstetrics and Gynecology,
Chicago, IL
- 1/02 “Obsetrical Anal Sphincter Lacerations: An Evidence Based Review”
-

- Presented at: : 34th Annual OB/GYN Post Graduate Conference, UNMH
- 2/03 “Medical Treatment of Urinary Incontinence in the Female”
Presented at: : Navajo Area Midwinter Conference on Women’s Health
Midwinter Conference, Telluride, CO
- 5/02 “Surgical Treatment of Genuine Stress Urinary Incontinence”
Presented at: Annual Meeting of the American College of Obstetrics and Gynecology,
Los Angeles, CA
- 5/03 “Surgical Treatment of Genuine Stress Urinary Incontinence”
“Obstetrical Anal Sphincter Lacerations: An Evidence Based Review”
Presented at: Annual Meeting of the American College of Obstetrics and Gynecology,
New Orleans, LA
- 5/03 “Sling Procedures for the Treatment of Stress Urinary Incontinence”
“Birth Injury and the Pelvic Floor”
Presented at: 74th Annual New England Obstetrical and Gynecologic Society
- 11/03 “Anal Incontinence and Obstetrical Anal Sphincter Lacerations: Identification and
Repair” UNMH CME Course, Albuquerque, NM
- 5/04 “Surgical Treatment of Genuine Stress Urinary Incontinence”
“Obstetrical Anal Sphincter Lacerations: An Evidence Based Review”
Presented at: Annual Meeting of the American College of Obstetrics and Gynecology
- 5/05 “Obstetrical Anal Sphincter Lacerations: Anatomy, Prevention, Sequelae and Repair:
A Course with “Hands-on” Repair Models”
Presented at: Annual Meeting of the American College of Obstetrics and Gynecology,
San Francisco, CA
- 11/05 “Pathophysiology of Urinary Incontinence” UNMH CME Course, Albuquerque, NM
- 5/06 “Obstetrical Anal Sphincter Lacerations: Anatomy, Prevention, Sequelae and Repair:
A Course with “Hands-on” Repair Models”
Presented at: Annual Meeting of the American College of Obstetrics and Gynecology,
Washington, DC
- 9/06 “Urinary Incontinence - How to Clinically Evaluate Stress and Urge” UNMH CME
Course, Albuquerque, NM
- 9/06 “Female Sexual Function and Pelvic Floor Dysfunction: An Overview” Presented at
the International Urogynecology Association Annual Meeting, Athens, Greece
- 5/07 “Obstetrical Anal Sphincter Lacerations: Anatomy, Prevention, Sequelae and Repair:
A Course with “Hands-on” Repair Models”
-

Presented at: Annual Meeting of the American College of Obstetrics and Gynecology, San Diego, CA

- 6/07 “Sexual Function After Surgery for Pelvic Floor Dysfunction” and “Sexual Arousal Disorder: A Case Presentation” Presented at the International Urogynecology Association Annual Meeting, Cancun, Mexico
- 9/07 "Painful Bladder Syndrome" UNMH CME Course, Albuquerque, NM
- 6/08 “Sexual Function Assessment in Women with Pelvic Floor Dysfunction Women.” International Urogynecological Association (IUGA) Roundtable, Ft. Lauderdale, FL.
- 9/08 “Female Sexual Function and Pelvic Floor Dysfunction: An Overview” Presented at the American Urogynecology Society Annual Meeting, Chicago, IL

WOMEN’S PELVIC SPECIALTY CARE (2009-present)

- 5/09 “Female Sexual Function and Dysfunction” and “Female Sexual Function and Pelvic Floor Dysfunction” Australian Gynaecological Endoscopy Society, Sydney, Australia
 - 6/09 “Female Sexual Function Questionnaires” and “Female Sexual Function after Surgery for Prolapse and/or Urinary Incontinence” International Urogynecology Association, Lake Como, Italy
 - 9/09 “Sex after Surgery for Pelvic Floor Dysfunction” and “Sex and the Older Women: Does Age Matter?” American Urogynecologic Society, Hollywood, FL
 - 11/09 “Female Sexual Function and Dysfunction” 2009 Wiggins ObGyn Lectureship, Albuquerque, NM
 - 8/10 “Assessment of Sexual Function in Women with Prolapse and Urinary Incontinence” and “Sex after Surgery for Pelvic Floor Dysfunction” International Urogynecology Association, Toronto, Canada
 - 11/12 “Anatomy of The Anal Sphincter”, “Conservative Treatment of Pelvic Organ Prolapse”, and “Questionnaire Use in Women with Pelvic Floor Dysfunction”. Jeddah, Saudi Arabia International Urogynecology Regional Symposium
 - 11/13 “You and Your Pelvic Floor” Lovelace Medical Systems
 - 5/14 “Impact of Pelvic Floor Dysfunction on Sexual Health” International Menopause Society Annual Meeting, Cancun, Mexico
 - 4/16 “Sex and the Presbyterian” First Presbyterian Church, Albuquerque Educational Symposium
-

7/17 “Female Sexual Function” , “Female Sexual Function in Women with Pelvic Floor Disorders”, “Urodynamic Assessment”, and “Conservative Treatment of Pelvic Organ Prolapse”, International Urogynecology Fellowship Training Program, Ghana, Africa

RESEARCH, TEACHING AND SERVICE INTERESTS.

My research interests encompass the area of gynecologic surgery, urogynecology and pelvic floor disorders. I have participated as a mentor and co investigator on a Research Allocation Committee Grant for Dr. Rebecca Rogers, to develop a questionnaire to evaluate sexual function in women with pelvic organ prolapse and/or urinary incontinence. My more recent research interests involve the evaluation of sexual health among women with pelvic floor dysfunction. This includes serving as the senior mentor for Dr. Rogers’ work in developing the PISQ and PISQ 12. More recently, I served as a co-investigator in the development of the PISQ IR and the work to elucidate its scoring. As the chair of the International Urogynecological Association Research Committee during the conduct of this work, I was responsible for coordinating the project as well as serving as a co-investigator and senior mentor. Currently, through the University of New Mexico, I am a co-investigator for a multi-center network grant from the Pelvic Floor Disorders Network involving collaborative research to discover the best treatment for pelvic floor disorders, as well as translational studies that investigate the pathogenesis of common urogynecologic problems.

Other projects include a randomized trial investigating gastrointestinal symptoms following routine gynecologic surgery, a randomized trial evaluating the effect of vasopressin on the incidence of postoperative infection, a randomized trial comparing 2 surgical methods for obstetrical anal sphincter laceration, and a prospective, multi-center trial investigating the use of antibiotic versus placebo on the incidence of postoperative urinary tract infection with use of suprapubic catheter following surgery for pelvic organ prolapse and/or urinary incontinence. I also have participated as a principle and co investigator on several pharmaceutical studies involving hormone replacement therapy, premenstrual syndrome and osteoporosis.

My teaching efforts have focused on urogynecology and gynecologic surgery as well as general Obstetrics/gynecology in formal lectures, didactics, the operating room, and formalized gynecology didactic sessions. I have also mentored several medical students and a total of 15 residents in research projects, including 4 which have been published, and 5 which have been presented as abstracts at national meetings. I have also participated in the UNMH fellowship program in urogynecology and pelvic floor disorders.

My service interests involve patient care and consultative services to other generalist physicians. I provide complete general gynecology and specialty, urogynecologic and pelvic floor disorder care. This includes out patient and surgical management of complex urinary incontinence and pelvic organ prolapse. I receive consultations and provide educational services to generalists from the city of Albuquerque and around the state. I am active in First Presbyterian Church, including participation as a sponsor/chaperone for the Youth Group and have served as an elected elder to the church session as well as a member of the Mission Committee. Additionally, I am on the board of The Mountain Fund, an organization that provides medical and other services to Nepal. I am also voluntary faculty for the International Urogynecologic Society Fellowship Training Program in Ghana, Africa.

Book Chapters:

1. **Kammerer-Doak DN**, Fromm LM, Schiff M. The Psychologic Aspects of the Female Life Cycle. Core Textbook of Obstetrics and Gynecology. Editor Dr. John Maddox, Mosby - Year Book, Inc., St. Louis, MO. 1997, **24**: pgs 236-43
2. Schiff M, Fromm L, McCarty T, **Kammerer-Doak D**, Roberts LW. Sexuality. In Mattox J, ed. Core Textbook of Obstetrics and Gynecology. St. Louis, MO. The C.V. Mosby Company, 1st Edition 1997
3. Smith HO, Genesen MC, **Kammerer-Doak DN**. Postoperative surveillance and perioperative prophylaxis. In: Perioperative and Supportive Care in Gynecologic Oncology: Evidence Based Management. Wily-Liss, Inc., 1st Edition 2000.

Scholarly articles in Refereed Journals:

1. **Kammerer-Doak DN**, Magrina JF, Nemiro JS, Lidner TK. Benign Gynecologic Condition Associated with CA-125 Level Greater Than 1,000U/ml:A Case Report. J Repro Med, 40;179 (1996).
 2. **Kammerer-Doak DN**, Sarto GE. What's New in Gynecology and Obstetrics. Journal of the American College of Surgeons, 182 (2) :107 (1996).
 3. **Kammerer-Doak DN**, Mao J. Vaginal Hysterectomy With and Without Morcellation: The University of New Mexico Hospital Experience. Obstet Gynecol, 88: 560 (1996).
 4. Smith HO, **Kammerer-Doak DN**, Barbo D, Sarto GE. Hormone Replacement Therapy in the Menopause: A Pro Opinion. CA-A Cancer Journal for Clinicians, 46: 343-363 (1996)
 5. **Kammerer-Doak DN**, Baurick K, Black W, Barbo D, Smith HO. Endodermal Sinus Tumor and Embryonal Carcinoma of the Ovary in a 53 Year Old Woman: A Case Report. Gyn Onc, 63; 133 (1996).
 6. **Kammerer-Doak DN**, Magrina J, Weaver A , Lee R. Vaginal Hysterectomy-With Versus Without Oophorectomy: The Mayo Clinic Experience. J. Pelvic Surgery, 2 (6): 304 (1996)
 7. Cornella JL, Larson TR, Lee RA, Magrina JF, **Kammerer-Doak DN**. Leiomyoma of the female urethra and bladder: Report of twenty-three patients and review of the literature. Am J Obstet Gynecol 176 (6): 1278 (1997).
 8. **Kammerer-Doak DN**, Dominguez C, Harner K, Dorin MH. Review of Surgical Repair of Fecal Incontinence and Correlation of Sonographic Anal Sphincter Integrity with Subjective Cure. J Repro Med 43:576 (1998).
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9. Tool A., **Kammerer-Doak DN**, Nguyen C, Cousin M. Postoperative Pain Relief Following Laparoscopic Tubal Sterilization With Silastic Bands. *Obstet Gynecol* 90:731-4 (1997).
 10. **Kammerer-Doak DN**, Cornella JL, Magrina JF, Stanhope CR, Smilack J., Osteitis Pubis Following Marshall Marchetti-Krantz Urethropy: A Pubic Osteomyelitis. *Am J Obstet Gynecol* 179: 586-90 (1998).
 11. **Kammerer-Doak DN**, Dorin MH, Rogers RG, Cousin MO, A Randomized Trial of Burch Retropubic Urethropy and Anterior Colporrhaphy for Stress Urinary Incontinence *Obstet Gynecol* 93 (1):75-78 (1999)
 12. Rogers RG, Gilson G, **Kammerer-Doak DN**, Labor Epidural and Active Management of Labor: Effects on Length of Labor and Mode of Delivery. *Obstet Gynecol* 93:995-998 (1999)
 13. **Kammerer-Doak, DN**, Wesol AB, Rogers RG, Dominguez CE, Dorin MH. A Prospective Cohort Study of Women After Primary Repair of Obstetric Anal Sphincter Laceration. *Am J Obstet Gynecol* 181:1317-23 (1999).
 14. Rogers RG, **Kammerer-Doak, DN**, Miller M, Byrn F, Conway S, Hall R. A Comparison of Ultrasound and Surgical Findings in Suspected Ectopic Pregnancy. *JDMS* 16:60-64 (2000).
 15. MacMillan S, **Kammerer-Doak, DN**, Rogers RG, Parker K. The Effect of Early Feeding on Gastrointestinal Symptoms Following Major Gynecologic Surgery. *Obstet Gynecol* 96:604-608 (2000).
 16. **Kammerer-Doak, DN**, Rogers RG. Endometrial Ablation: Electrocautery and Laser Techniques. *Clin Obstet Gynecol* 43:561-74 (2000).
 17. Rogers RG, **Kammerer-Doak DN**, Villarreal AL, Qualls C. A New Instrument to Measure Sexual Function in Women with Urinary Incontinence or Pelvic Organ Prolapse. *Am J Obstet Gynecol* 184:552-558 (2001).
 18. Rogers RG, Villarreal AL, **Kammerer-Doak DN**, Qualls C. Sexual Function In Women with and Without Urinary Incontinence and/or Pelvic Organ Prolapse. *In J Urogynecol* 12:361-365(2001).
 19. **Kammerer-Doak DN**, Rogers RG, Johnson-Maybach J, Traynor-Mickelson M. Vasopressin as an Etiologic Factor for Infection in Gynecologic Surgery: A Randomized Double-Blind Placebo Controlled Trial. *Am J Obstet Gynecol* 185:1344-1348(2001).
 20. Lewis-Bliehall C, Rogers RG, **Kammerer-Doak DN**, Conway SC, Amaya C, Byrn F. Medical vs. Surgical Treatment of Ectopic Pregnancy: The University of New Mexico's Six-year Experience. *J Reprod Med* 46:983(2001).
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21. **Kammerer-Doak, DN**, Rogers RG, Bellar B. Vaginal Erosion of Cadaveric Vascia Lata Following Abdominal Sacrocolpopexy and Suburethral Sling Urethropexy. *Int Urogynecol J Pel Floor Dis* 13:106(2002).
 22. Rogers RG, **Kammerer-Doak DN**, Spearman MJ. Obstetrical Anal Sphincter Lacerations: An Evidence Based Approach. Part 1: Anatomy and Risk Factors. *The Female Patient* 27(4):21(2002).
 23. Rogers RG, **Kammerer-Doak DN**. Obstetrical Anal Sphincter Lacerations: An Evidence Based Approach. Part 2: Repair Techniques. *The Female Patient* 27(5):31(2002).
 24. **Kammerer-Doak DN**, Rogers RG. Surgical Treatment of Genuine Stress Urinary Incontinence. Part 1. *The Female Patient* 27(10):11(2002).
 25. Rogers RG, **Kammerer-Doak DN**. Surgical Treatment of Genuine Stress Urinary Incontinence. Part 2. *The Female Patient* 27(11):37(2002).
 26. Rogers RG, Coates KW, **Kammerer-Doak DN**, Khalsa S, Qualls C. A Short Form of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). *Int Urogynecol J Pel Floor Dis* 14:164(2003).
 27. Taylor SM, Romero AA, **Kammerer-Doak DN**, Qualls C, Rogers RG. Abdominal Hysterectomy for the Enlarged Myomatous Uterus Compared with Vaginal Hysterectomy with Morcellation. *Am J Obstet Gynecol*. 189:1579-83 (2003).
 28. Rogers RG, **Kammerer-Doak DN**, Olsen A, Thompson PK, Walters MD, Lukacz ES, Qualls C. A Randomized, Double-blind, Placebo-Controlled Comparison of the Effect of Nitrofurantoin Monohydrate Macrocrystals on the Development of Urinary Tract Infections after Surgery for Pelvic Organ Prolapse and/or Stress Urinary Incontinence with Suprapubic Catheter Catheterization. *Am J Obstet Gynecol*. 191:812-7 (2004).
 29. Rogers RG, **Kammerer-Doak DN**, Darrow A, Murray K, Olsen A, Barber M, Qualls C. Sexual Function after Surgery for Stress Urinary Incontinence and/or Pelvic Organ Prolapse: A Multicenter Prospective Study. *Am J Obstet Gynecol*. 191:206-10 (2004) and *Am J Obstet Gynecol*. 195:e1-4 (2006)
 30. Garcia V, Rogers RG, Kim SS, Hall RJ, **Kammerer-Doak DN**. Primary Repair of Obstetric Anal Sphincter Laceration: A Randomized Trial of Two Surgical Techniques. *Am J Obstet Gynecol*. 192:1697-701 (2005).
 31. Rogers RG, Lebkuchner U, **Kammerer-Doak DN**, Thompson PK, Walters MD, Nygaard IE. Obesity and Retropubic Surgery for Stress Incontinence: Is There Really an Increased Risk of Intraoperative Complications? *Am J Obstet Gynecol* . 195:1794-8 (2006)
 32. Komeu YM, Rogers RG, **Kammerer-Doak DN**, Barber MD, Olsen AL. Posterior Repair and Sexual Function. *Am J Obstet Gynecol* . 197:101-6 (2007)
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33. Komesu YM, Rogers RG, **Kammerer-Doak DN**, Olsen AL, Thompson PK, Walters MD. Clinical Predictors of Urinary Retention after Pelvic Reconstructive and Stress Urinary Incontinence Surgery. *J Reprod Med* 52:611-5 (2007)
34. **Kammerer-Doak DN**, Rogers RG. Female Sexual Function and Dysfunction. *Obstet Gynecol Clin North Am*. 2008 Jun;35(2):169-83, vii. Review.
35. **Kammerer-Doak DN**. Assessment of Sexual Function in Women with Pelvic Floor Dysfunction. *Int Urogynecol J Pelvic Floor Dysfunct*. 2009 20(S):S45-50.
36. Rogers RG, Rockwood TH, Constantine ML, Thakar R, **Kammerer-Doak DN**, Pauls RN, Parekh M, Ridgeway B, Jha S, Pitkin J, Reid F, Sutherland SE, Lukacz ES, Domoney C, Sand P, Davila GW, Espuna Pons ME. A new measure of sexual function in women with pelvic floor disorders (PFD): the Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR). *Int Urogynecol J*. 2013 Jul;24(7):1091-103.
37. Rockwood TH, Constantine ML, Adegoke O, Rogers RG, McDermott E, Davila GW, Domoney C, Jha S, **Kammerer-Doak D**, Lukacz ES, Parekh M, Pauls R, Pitkin J, Reid F, Ridgeway B, Thakar R, Sand PK, Sutherland SE, Espuna-Pons M. The PISQ-IR: considerations in scale scoring and development. *Int Urogynecol J*. 2013 Jul;24(7):1105-22.
38. **Kammerer-Doak D**, Rizk DE, Sorinola O, Agur W, Ismail S, Bazi T. Mixed urinary incontinence: International Urogynecological Association Research and Development Committee Opinion. *Int Urogynecol J* 2014;10:1303-12
39. Kantner G, Rogers RG, Pauls RN, **Kammerer-Doak D**, Thakar R. A strong pelvic floor is associated with higher rates of sexual activity in women with pelvic floor disorders. *Int Urogynecol J* 2015;26:991-6.
40. Pauls RN, Rogers RG, Parekh M, Pitkin J, **Kammerer-Doak D**, Sand P. Sexual function in women with anal incontinence using a new instrument: the PISQ-IR. *Int Urogynecol J* 2015;26:657-63.
41. Bazi T, Takahashi S, Ismail S, Bø K, Ruiz-Zapata AM, Duckett J, **Kammerer-Doak D**. Prevention of pelvic floor disorders: International Urogynecological Association Research and Development Committee opinion. *Int Urogynecol J* 2016 Mar 12 [Epub ahead of print]
42. Ismail S Duckett J, Rizk D, Sorinola O, **Kammerer-Doak D**, Contreras-Ortiz O, et al. Recurrent pelvic organ prolapse: International Urogynecological Association Research and Development Committee opinion. *Int Urogynecol J* 2016 Jul 5 [Epub ahead of print]
43. **Kammerer-Doak DN**, Svabki K, Bazi T. Variability in practice patterns in stress urinary incontinence and pelvic organ prolapse: results of an IUGA survey. *Int Urogynecol J*. 2016 Oct 17.

Other Scholarly Products:

1. **Kammerer-Doak DN**, Hormone Replacement Therapy in Perimenopausal and

Postmenopausal Women. Video by the Video Journal of the American College of Obstetrics and Gynecology Volume X, Number 3, 1997

2. **Kammerer-Doak DN**, Rogers RG. Female Sexual Function and Dysfunction. *Obstet Gynecol Clin North Am.* 2008 Jun;35(2):169-83.

Refereed Abstracts/ Presentations:

1. **Kammerer-Doak DN**, Nguyen C, Tool A. Postoperative Pain Relief Following Laparoscopic Tubal Sterilization With Falope Rings. Oral presentation, Society of Laparoendoscopic Surgeons, Endo Expo '96, December 5 - 7, 1996, Orlando, Florida.
 2. **Kammerer-Doak DN**, Harner K, Dominguez C, Dorin M. Vaginal Ultrasonographic Evaluation of the Anal Sphincter Complex in Women Following Surgical Repair. Poster Presentation, The American College of Obstetricians and Gynecologists, 1996 District VIII-IX Albuquerque, New Mexico.
 3. **Kammerer-Doak DN**, Cornella J, Magrina J, Stanhope R. Osteitis Pubis Following Marshall-Marchetti-Kranz Retropubic Urethropexy. Oral presentation, the American Urogynecologic Society, 17th Annual Scientific Meeting, New Orleans, Louisiana, October, 1996.
 4. **Kammerer-Doak DN**, Dorin M, Rogers R, Cousin M. A Prospective Randomized Comparison of the Burch Retropubic Urethropexy and the Anterior Repair for the Treatment of Genuine Stress Urinary Incontinence. Oral presentation, the American Urogynecologic Society, 18th Annual Scientific Meeting, Tucson, Arizona, September 1997.
 5. Rogers RG, Gilson G, **Kammerer-Doak DN**. Labor epidural and active management of labor: Effects on length of labor and mode of delivery. American College of Obstetricians & Gynecologists (ACOG) Annual Meeting, New Orleans, May, 1998.
 6. Rogers RG, **Kammerer-Doak DN**, Qualls C, Villarreal A. Development of a Sexual Function Questionnaire: A Preliminary Report. Oral Presentation, the American Urogynecologic Society, 19th Annual Scientific Meeting, Washington DC, November 1998
 7. Rogers RG, Miller M, **Kammerer-Doak DN**, A Comparison of Ultrasound and Surgical Findings in Suspected Ectopic Pregnancy. Oral Presentation, the Pacific NW Review & American College of Obstetricians and Gynecologists District VIII & IX Meeting, Portland, Oregon, October 1998.
 8. **Kammerer-Doak DN**, Wesol A, Rogers RG, Dominguez C, Dorin MH. A Prospective Cohort Study Following Primary Repair of Obstetrical Anal Sphincter Laceration. Oral Presentation, Society of Gynecologic Surgeons Annual Meeting San Diego, California, February 1999.
 9. Rogers, RG, **Kammerer-Doak, DN**, Villareal, A, Coates, K, Qualls, C., A New Instrument To Measure Sexual Function In Women With Urinary Incontinence And/Or Pelvic Organ Prolapse. Oral Presentation, American Urogynecologic Society 20th Annual Meeting, San Diego, California,
-

October, 1999.

10. **Kammerer-Doak, DN**, Rogers, RG, Beller, B. Cadaveric Fascia Lata Erosion Following Abdominal Sacrospinopexy And Suburethral Sling Urethropexy. Oral Presentation, American Urogynecologic Society 20th Annual Meeting, San Diego, California, October, 1999.
 11. Rogers, RG, **Kammerer-Doak, DN**, . A Method For Suture Ligature In Deep Spaces. Poster Presentation, American Urogynecologic Society 20th Annual Meeting, San Diego, California, October, 1999.
 12. Rogers RG, **Kammerer-Doak DN**, Villarreal AL, Qualls. Sexual Function in Women with and Without Urinary Incontinence and/or Pelvic Organ Prolapse. Poster Presentation, Central Association Obstetricians and Gynecologists 67th Annual Meeting, Maui, Hawaii, October 1999.
 13. MacMillan S, **Kammerer-Doak DN**, Rogers RG, Parker K. Postoperative Management of Gynecologic Surgery Patients: The Effect of Early Feeding on the Incidence of Gastrointestinal Symptoms. Poster Presentation, Society of Gynecologic Surgeons 26th Annual Meeting, New Orleans, Louisiana, February 2000.
 14. Rogers RG, Qualls C, **Kammerer-Doak DN**, Coates, K. Short Form to Assess Sexual Function in Women with Urinary Incontinence and/or Pelvic Organ Prolapse: The PISQ-11. Oral Presentation, American Urogynecologic Society 21st Annual Meeting, Hilton Head, South Carolina, October, 2000.
 15. Rogers RG, Lewis-Bliehall C, **Kammerer-Doak D**. A method for entering the peritoneum during uterosacral vaginal vault suspension. American Urogynecologic Society (AUGS) Annual Scientific Meeting in Hilton Head, SC, October 2000. International Urogynecology Journal 12(Suppl 1):P18b, 2000.
 16. **Kammerer-Doak DN**, Rogers R, Johnson J, Mickelson MT. Vasopressin as an Etiologic Factor for Infection in Gynecologic Surgery: A Randomized Double Blind Placebo Controlled Trial. Oral Presentation, Society of Gynecologic Surgeons 27th Annual Meeting, Lake Buena Vista, FL, March 2001.
 17. S Taylor, **DN Kammerer-Doak**, A Romero, C Qualls, RG Rogers. Abdominal Hysterectomy for the Enlarged Myomatous Uterus Compared with Vaginal Hysterectomy with Morcellation. Oral Presentation, Society of Gynecologic Surgeons 29th Annual Meeting, Anaheim, CA March 2003.
 18. R.G. Rogers, **D.N. Kammerer-Doak**, A. Olsen, P.K. Thompson, M Walters, M. Lukacz. A Randomized Double-Blind Placebo Controlled Comparison of the Effect of Macrobid on the Development of Urinary Tract Infections Following Surgery for Pelvic Organ Prolapse and/or Genuine Stress Urinary Incontinence with Suprapubic Catheter. Oral Presentation, American Urogynecologic Society 23rd Annual Meeting, Hollywood, FL, September 2003.
 19. R. Rogers, **D. Kammerer-Doak**, A. Darrow, K. Murray, M. Barber, A. Olsen, I. Nygaard, Sexual Function after Surgery for Stress Urinary Incontinence and/or Pelvic Organ Prolapse: A Multi-Center Prospective Study. Oral Presentation, American Urogynecologic
-

Society 23rd Annual Meeting, Hollywood, FL, September 2003

20. Rogers RG, Garcia V, Hall RJ, Kim SS, **Kammerer-Doak DN**. Primary repair of obstetrical anal sphincter laceration: a prospective randomized trial of two surgical techniques. Society of Gynecologic Surgeons (SGS)/American Urogynecology Society (AUGS) Joint Conference, San Diego, CA, July, 2004.
21. Komesu YM, Rogers RG, **Kammerer-Doak DN**, Walters MD, Thompson PK, Olsen AL, Ketani LH. Clinical predictors of prolonged length of suprapubic catheterization following surgery for pelvic floor reconstruction and/or stress urinary incontinence. Society of Gynecologic Surgeons (SGS)/American Urogynecology Society (AUGS) Joint Conference, San Diego, CA, July, 2004.
22. Rogers R, Lebkuechner U, **Kammerer-Doak D**, Thompson P, Walters M. Obesity and retropubic surgery for stress urinary incontinence: is there really an increased risk of intra-operative complications? 32nd Society of Gynecologic Surgeons (SGS), Tucson, AZ, April, 2006.

Past Grant/Contract Funding:

1. A New Instrument to Measure Sexual Function in Incontinent Women

Investigators: R.G. Rogers
D.N. Kammerer-Doak
Sponsor: RAC Grant
Amount: \$15,060.00 direct costs

February 1998 - 1999

2. A Prospective Randomized Trial Evaluating the Use of Macrobid Prophylaxis for Prevention of Urinary Tract Infection Following Surgery for Urinary Incontinence and/or Pelvic Organ Prolapse Utilizing Suprapubic Catheter.

Investigators: D.N. Kammerer-Doak
R.G. Rogers
Sponsor: Proctor and Gamble
Amount: \$25,600.00 direct costs

1999-2003

3. Protocol 97036: A multicentre, double-blind, randomized, placebo controlled, parallel group study to evaluate the efficiency of a monophasic oral contraceptive preparation, containing Drospirenone 3 mg and Ethinyl Estradiol 30 ug, in the treatment of premenstrual syndrome (PMS)

Investigators: M. Dorin
D.N. Kammerer-Doak
C. Dominguez
R. Rogers
Sponsor: Berlex
Amount: \$85,070.00 direct costs

1997 - 2000

4. 713-B-309-US, the Hope Study, A prospective double blind, randomized study of the safety and efficacy of lower doses of Premarin and Medroxyprogesterone acetate in postmenopausal women.
Investigators: M. Dorin
D.N. Kammerer-Doak
R. Rogers
Sponsor: Wyeth-Ayerst
Amount: \$200,000.00 direct costs
1995 –1999
5. A multicenter, randomized, double-blind, parallel group, dose-ranging study to evaluate the safety of a cyclophasic hormone replacement therapy regimen of estradoil and norgestimate and its effect on endometrial histology and vaginal bleeding in postmenopausal women.
Investigators: D.N. Kammerer-Doak
Sponsor: The R.W. Johnson Pharmaceutical Research Institute
Amount: \$108,000.00 direct costs
February 1996 – May 31, 1998
6. A triple -blind, randomized, placebo-controlled, parallel-group multicenter study to evaluate the efficacy and tolerability of the addition of alendronate sodium to ongoing hormone replacement therapy in the treatment of osteoporosis in postmenopausal women.
Investigators: D.N. Kammerer-Doak
M. Dorin
Sponsor: Merck & Co., Inc.
Amount: \$37,042.00 direct costs
November, 1995 – January 1, 1998

Ongoing Research Support:

UHD069025A NIC

2011 – 2016

Rogers (PI)

Pelvic Floor Disorder's Network

This multi-center network grant from the Pelvic Floor Disorders Network trials is awarded to conduct collaborative research to discover the best treatment for the appropriate patient at the right time as well as to participate in translational studies that investigate the pathogenesis of common urogynecologic problems.

Role: Co-Investigator

Mentoring: Other Faculty/Fellows

Rebecca G. Rogers

Activities: Director of Pelvic Surgery/Urogynecology Fellowship
development of clinical and operative skills in subspecialty of Urogynecology and Pelvic Floor Disorders, supervision of preparation of invited lectures, mentorship in design, method and data analysis of research projects.

Dates: July 1, 1996August 30, 1998

Outcomes:

1. Graduation from fellowship, September 1, 1998
-

2. Research Allocation Committee Grant: A New Instrument to Measure Sexual Function in Incontinent Women
Principle Investigator: R. Rogers
DN Kammerer-Doak

Teaching/Education

Undergraduate Medical Student Mentoring

1. Jonathan Pugmire

December 1997 – January 1998

Outcome: Supervision of chart review, abstract and data entry for research project:

“Postoperative Management of Gynecologic surgery Patients: The Effect of Immediate feeding on the Incidence of Gastrointestinal Symptoms.”

2. Sarah Deletorre

9/98 – 4/99

Outcome: Supervision of chart review, abstract and data entry for research project:

“Postoperative Management of Gynecologic surgery Patients: The Effect of Immediate Feeding on the Incidence of Gastrointestinal Symptoms.”

Classroom / Laboratory Teaching

“Pelvic Masses”, Phase II Obstetrics /Gynecology rotation medical student lecture 1996 – 1999

Cadaveric Dissections of the Female Pelvic Floor – laboratory session for residents/fellow July 1997

Resident Teaching and Mentoring

MT Mickelson

Vasopressin as an Etiologic Factor for Infection in Gynecologic Surgery: A Randomized Double Blind Placebo Controlled trial
Senior research project, presented 6/98

Adrianne Wesol

Vaginal Probe Anal Sonography Following Primary Repair of Obstetrical Anal Sphincter Laceration.

Senior research project, presented 6/98

Awarded “Best Research Project”

Oral presentation, Society Gynecologic Surgeons, 2/99

Published Am J Obstet Gynecol 181:1317-23 (2000).

RG Rogers

AVillarreal

Development of a Sexual Function Questionnaire: A Preliminary Report.

Mentor for Dr. Rogers (fellow) and Dr. Villarreal (resident)

Abstract presented at American Urogynecologic Society National Meeting 11/98, Awarded Best Research Project

Kathleen Harner

Review of Surgical Repair of Fecal Incontinence and Correlation of Sonographic Anal Sphincter Integrity with Subjective Cure:

Senior Research Project, Presented 6/96

Poster Presentation

District VIII – IX American College of Obstetricians and Gynecologists Meeting, 1996

Published: J Repro Med 43:576 (1998).

Audrey Tool

Postoperated Pain Relief Following Laparoscopic Tubal Sterilization With Silastic Bands.

Senior research project Presented 6/97

Awarded “Best Research Project”

Oral abstract presentation,

Society of Laparoendoscopic Surgeons, Endo Expo '96 December 5-7, 1996, Orlando, Florida

Published Obstet Gynecol 90:731-4 (1997).

Alexandra Klikoff

Comparison of Breast Feeding Performance and Secretion of Prolactin and Oxytocin in Lactating Women Using Progestin-Only Oral Contraceptives, Low-dose Combination Oral Contraceptives, and Non-Hormonal Contraception.

Senior research project presented 6/97.

Susan Conway

Medical versus Surgical Management of Ectopic Pregnancy at UNM Health Sciences Center: A Retrospective Review

Senior Research Project; Presented 6/97

Michelle Miller

A Comparison of Ultrasound and Surgical Findings in Suspected Ectopic Pregnancy

Senior Research Project; Presented 6/98

Oral Abstract Presentation Pacific NW Review & American College of Obstetricians and Gynecologists District VIII & IX Meeting, Portland, Oregon, October, 1998 Published, JDMS 16:60-64 (2000).

Cuong M. Nguyen

Postoperative Pain Relief Following Laparoscopic Tubal Sterilization with Falope Rings: A Randomized Double Blind Placebo Controlled Comparison of the Effect of Intramuscular Ketorolac and local Bupivacaine

Senior Research Project; Presented 6/96 (preliminary results)
Awarded "Best Research Project", 2nd Place.

Kathy Brown

Abdominal Hysterectomy for the Enlarged Myomatous Uterus Compared with Vaginal Hysterectomy with Morcellation
Senior Research Project; Presented 6/96

Karl Baurick

Endodermal Sinus Tumor and Embryonal Carcinoma of the Ovary in a 53-year-old Women: A Case Report – Written 6/95 – 3/96
Published Gyn Onc 63: 133 (1996)

Jenny Mao

Vaginal Hysterectomy with and without morcellation: The UNMH Experience
Senior Research Project , Presented 6/95
Published Obstet Gynecol 88:560 (1996)

Susan MacMillan

Postoperative Management of Gynecologic Patients:
The Effect of Immediate Feeding on Gastrointestinal Symptoms
Senior Research Project: Presented 1999, Best Research Project
Poster Presentation, Society of Gynecologic Surgeon, 2000
Published Obstet Gynecol 2000

Suzy Kim

Primary Repair of Obstetrical Anal Sphincter Laceration: A Prospective Randomized Trial of Two Surgical Techniques
Senior Research Project: Presented 2000

Jacqueline Johnson

Vasopressin as an Etiologic Factor for Infection in Gynecologic Surgery: A Randomized Double Blind Placebo Controlled Trial
Senior Research Project: continuation of previous project, Presented, 2000, best research project.

Byrke Bellar

Vaginal Erosion of Cadaveric Vascia Lata Following Abdominal
Sacrocolpopexy and Suburethral Sling Urethropexy
Senior Research Project, Presented 2001, best research project
Accepted for publication 2002, Int Urogynecol J

Curriculum development or educational administrative positions

Faculty Instructor Urogynecology and Pelvic Floor Disorder Fellowship
UNMH 2002-present, accredited 2008

Developed and directed fellowship in Urogynecology and Pelvic Floor
Disorders, 1996-1998

Developed and coordinated Gynecology noontime didactic: 1 hour
session with review of literature in gynecologic topics, including
statistical analysis, Obstetric and Gynecology Morbidity and Mortality
1993 –1999

Committees

Operating Room Committee, Lovelace Health Systems, 1999-2008

Surgical Services Committee, University of New Mexico Hospital, 1993
-1999

Gynecological Statistics Committee, Department of Obstetrics and
Gynecology, 1993 – 1995

Research Committee, Department of Obstetrics and Gynecology, 1998-
1999

Clinical Research Center Advisory Committee, University of New
Mexico Hospital, May 1996 - 1999

Faculty Senator, The University of New Mexico Faculty Senate,
1997 – 1999

Membership Committee, Central Association of Obstetricians and
Gynecologists, 1998-2000.

Mission Committee, First Presbyterian Church, Albuquerque, NM,
1998-2009.

Elder, Session of First Presbyterian Church, Albuquerque, NM 2003-
2006.

The Mountain Fund Board Member 2007-present

IUGA Research Committee Member 2007-2016, Chair 2011-2015
